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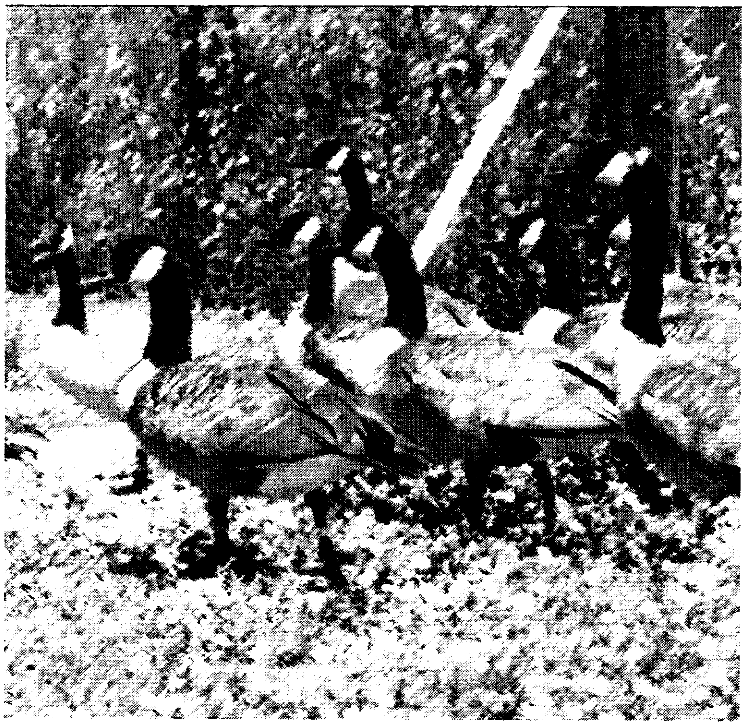
ENVIRONMENTAL
ASSESSMENT

Multi-center Field Study of Nicarbazin Bait for use in the Reduction in Hatching of Eggs Laid by Local Canada Goose Flocks



January 2004

ENVIRONMENTAL ASSESSMENT

Multi-center Field Study of Nicarbazin Bait for use in the Reduction in Hatching of Eggs Laid by Local Canada Goose Flocks

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January 2004

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CHAPTER 1: PURPOSE AND NEED FOR ACTION

1.1 INTRODUCTION

While all wildlife are valuable natural resources, some species of wildlife can cause problems with human interests. Many times, the wildlife species that cause problems are ones that have adapted to, and thrive in, the presence of people. Individuals/groups of Canada geese (*Branta canadensis*) that have formed resident year-round populations fit this depiction and are considered overabundant in many areas of the U.S., particularly in suburban and urban areas. The establishment of many Canada goose populations throughout the U.S. has occurred primarily because of re-introduction and transplant programs (Oberheu, 1973, Blandin and Heusmann 1974, Ankney 1995). These programs were so successful that Canada geese established large resident breeding populations in many urban centers, including areas where they had not bred or over-wintered in the past, creating an increased number of conflicts between human interests and the geese Conover and Chasko, 1985; Hindman and Ferrigno, 1990; Ankney, 1995). The U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Wildlife Services (WS), National Wildlife Research Center (NWRC) has personnel with the experience and expertise to conduct research and to develop practical methods or techniques to resolve problems caused by wildlife, including addressing the overabundance of resident Canada geese. WS operations personnel are trained to apply these and other methods of mitigating wildlife-human conflicts throughout the U.S. while minimizing environmental impacts.

In the U.S., Canada geese are a migratory bird and protected under the Migratory Bird Treaty Act which is administered by the United States Fish and Wildlife Service (USFWS). USFWS has recognized the growing problem of resident Canada geese and completed a Draft Environmental Impact Statement (DEIS) for the management of resident Canada geese (USFWS, 2002). The DEIS evaluates strategies to reduce, manage, and control both individuals and groups/populations of resident Canada geese and the damage they cause in the continental U.S. WS was a cooperating agency in drafting the DEIS because WS has legislative authority and operational programs in many states that respond to requests for assistance to abate Canada goose damage. The DEIS thoroughly discusses the problems associated with Canada geese, and the reader is referred to that document for a detailed discussion of the problem.

The following document is an Environmental Assessment (EA) that describes and analyzes WS and NWRC involvement in Canada goose damage management research. While the USFWS is clearly responsible for managing this species, WS is responsible for responding to damage or conflict requests. NWRC assists WS operations through research and development of methods and techniques used to resolve problems. For WS operations and other wildlife managers, the wider the array of methods from which to select a strategy to respond to problems, the more effective management personnel will be in providing solutions to human-wildlife interactions.

1.1.1 Background. Across the U.S., wildlife habitat has substantially changed as human populations have expanded and land has been transformed to meet varying human needs. These changes often compete with wildlife and have inherently increased the potential for conflicts between wildlife and people. Some species of wildlife have adapted to and even thrive in the presence of humans and the changes that have been made. These adaptable species, in particular, are often responsible for the majority of conflicts between humans and wildlife. USDA/APHIS/WS is directed by law to protect American agriculture and other resources from damage associated with wildlife. The primary statutory authority for WS is the Animal Damage Control Act of 1931 (7 U.S.C. 426-426c; 46 Stat. 1468), as amended in the Fiscal Year 2001 Agriculture Appropriations Bill, which is described in Section 1.8.1.

Wildlife damage management (WDM) is defined as the alleviation of damage or other problems caused by wildlife (Leopold, 1933; The Wildlife Society, 1990; Berryman, 1991). WS uses an Integrated WDM (IWDM) approach (sometimes referred to as "Integrated Pest Management") which is described in Volume 4, Chapter 1, pages 1-7 of the WS Final Environmental Impact Statement (FEIS, USDA, 1997). This includes many non-lethal strategies (such as the modification of habitat and animal behavior), and sometimes lethal control of the offending animal(s) or local populations of the offending species. Optimizing the efficacy of WDM methods used by WS and the development of new methods is an important mission of the NWRC.

The National Wildlife Research Center

NWRC is the only federal institution devoted to the development and improvement of methods and techniques used to resolve problems that are caused by the interaction of wild animals and society. A primary mission for the NWRC is to apply scientific expertise to the development of practical methods to resolve human-wildlife conflicts and to maintain the quality of the environments humans share with wildlife. NWRC objectives include increasing the number and variety of effective methods and techniques available for wildlife managers through:

- Assessing damage and other problems caused by wildlife to agriculture, the environment, and human health and safety;
- Investigating the biology and behavior of problem animals;
- Evaluating the impact of wildlife management practices on wildlife and the environment;
- Developing and improving technology to reduce wildlife problems;
- Supporting registration of chemicals and drugs used to manage wildlife;
- Provide scientific consultation and specialized technical training;
- Transferring scientific and technical information to the public and private sectors;
- Providing scientific guidelines on wildlife damage for use by regulatory agencies;
- Keeping abreast of latest technologies and their potential applications to wildlife damage;
- Developing cooperative research and training with other organizations; and
- Addressing priority needs of user groups and the public.

The WS Policy Manual[1] reflects the mission of the NWRC and provides guidance for engaging in WDM research activities. Before WDM research is conducted in the field, *Agreements for Control* must be executed by WS and the land owner/administrator/agency representative. WS cooperates with wildlife management

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1 **WS Policy Manual** - Provides guidance for WS personnel to conduct wildlife damage management activities through Directives. WS Directives referenced in this EA can be found in the manual but will not be referenced in the Literature Cited Section.

agencies, universities, private companies and others, when appropriate and as requested, to combine efforts to effectively and efficiently research methods for resolving wildlife damage problems. NWRC is also responsible for conducting its research in compliance with all applicable federal, state and local laws, and Memorandums of Understanding (MOU's) between WS and other agencies.

1.2 PURPOSE

This EA analyzes research on nicarbazin [CAS 330-95-0/4,4'-dinitrocarbanilide (DNC, CAS 587-90-6)/ 2-hydroxy-4,6-dimethylpyrimidine (HDP, CAS 108-79-2) (1:1)] as an infertility agent for Canada geese. NWRC and [redacted] have prepared this EA to facilitate planning, interagency coordination, streamline program management, and clearly communicate with the public and regulators the analysis of potential cumulative impacts resulting from this research. The analysis area encompasses approximately 10 sites selected in Oregon (5 west of the Cascades and 5 east of the Cascades) where growing numbers of Canada geese are currently causing problems for property owners. WS has obtained written permission from the property owners to use these sites for its research activities. These sites were selected because they have had identified damage problems, limited public access, and at least ten breeding and nesting pairs of Canada geese. Alternate sites have also been selected should one or more sites fail to have the required number of breeding pairs for the study in 2004. Nicarbazin bait, should it be found to be an effective tool for Canada goose management, is intended for use only in the contiguous 48 states of the U.S.

Use of baits containing nicarbazin will allow the numbers of small to moderate sized groups of Canada geese to be controlled by reducing the hatchability of eggs laid by treated geese without requiring the location of each individual nest to be determined. One method for controlling Canada goose population growth has been to oil or addle eggs (Cummings et al., 1997). Egg oiling techniques were successfully investigated and improved by the NWRC, resulting in a new label for this use under Section 25(b) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, and described in a WS Technical Note in 1996. To successfully oil or addle eggs, each individual nest must be located and monitored until the goose has finished laying eggs and begins to incubate, at which point the eggs are oiled or addled. This can be difficult because Canada geese often nest in areas with limited access, including islands in ponds or rivers, thick areas of brush or grass, or similar places. Baits containing nicarbazin will be offered at centralized locations when the Canada geese are beginning to nest, thus treating several breeding pairs of geese in the area at the same time without having to locate individual nests.

Research on the development of nicarbazin as a Canada goose fertility control agent was partially funded by congressional mandate in the WS budget for FY-2000. Since that time, the NWRC has been directed to develop infertility agents for a variety of avian species. Small-scale field studies to investigate the use and proper concentration of nicarbazin in baits for reducing the hatchability of Canada goose eggs were approved by state and federal wildlife agencies and have been conducted in Colorado (Yoder et al., unpubl data, 2003), Nebraska (VerCauteren et al., 2000), Minnesota (VerCauteren, unpubl data, 2003), New York (Curtis, et al., 2001) and Wisconsin (VerCauteren et al., 2002). Several organizations that are concerned with animal welfare (i.e., The Humane Society of the United States, Geese Peace, and the Coalition to Prevent Destruction to Canada Geese) advocate non-lethal means to control Canada geese such as infertility agents and egg oiling or addling on their web sites. This evidence suggests that research in the arena of contraceptive or infertility agents for Canada geese is supported and is being requested by the interested public.

1.3 NEED FOR ACTION

The need for action is based on the necessity for the WS program and other wildlife managers to have a variety of scientifically proven, effective and environmentally safe Canada goose damage management methods or techniques that enable users to effectively protect property, natural resources, and human health and safety in urban, suburban, and other developed areas. Every situation or site with problems associated with Canada geese typically requires a unique strategy and often a variety of methods to reduce damage. Although a variety of methods exist to resolve damages to resources from Canada geese, the array of methods does not include an oral contraceptive such as nicarbazin. An oral contraceptive would be a very useful tool to assist with managing Canada goose damage at certain sites. NWRC has the scientific experience and expertise to determine if and how nicarbazin can be used to effectively resolve problems with geese.

Effective non-lethal wildlife damage management methods are preferred to lethal methods if they are practical, biologically sound, and cost-efficient. At a site that has a small group of Canada geese, nicarbazin baits could be used to maintain static goose numbers and keep damage levels at a minimum. Where Canada geese are overabundant and are causing unacceptable damage, nicarbazin could also be used. Although it probably would be used in conjunction with other population management methods to reduce both the goose numbers and associated damage, and to maintain them both at an acceptable level.

To understand the need for action, it is also important to have knowledge about the Canada goose population in the contiguous 48 states. The need for action is based on Canada goose problems that are construed by resource owners and wildlife managers as damage. Full accounts of the life histories for these species can be found in the USFWS DEIS (2002) and avian reference books. Some background information is given below to help the reader understand the significant rise in the Canada goose population in the U.S.

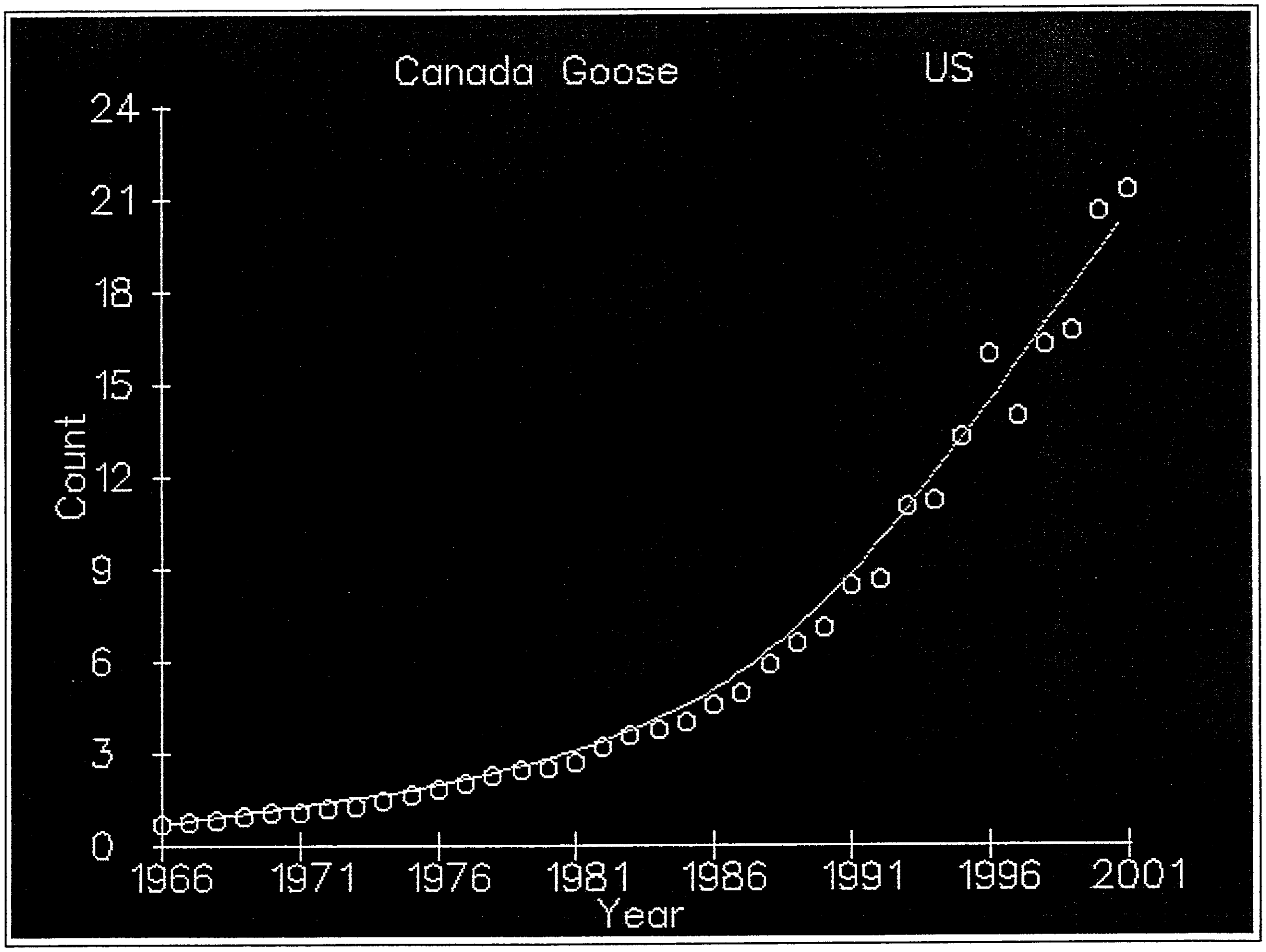
1.3.1 The Canada Goose Population in the United States

Canada geese are classified as a protected species in the U.S. by the USFWS and state game agencies. In the continental U.S., Canada geese populations have risen significantly (Figure 1-1) over the past 35 years. The overabundance of Canada geese in many urban areas has been human-caused, albeit unintentional and indirect (Ankney, 1996). Historically, breeding populations of Canada geese were found only in certain regions of the U.S. However, because of re-introductions and transplant programs throughout the U.S., Canada geese have considerably expanded their breeding range. In addition, Canada geese have a low mortality rate in urban areas and populations can grow exponentially where they are left unchecked.

Canada geese are primarily herbivorous. They graze on plants or parts of plants that are high in protein such as grass shoots, flowers, seed heads, and aquatic vegetation. They can be found in a wide variety of areas, but are mostly associated with open grasslands and aquatic areas. As a result of their habitat preference and diet, many urban areas throughout the United Sates are virtual goose paradises consisting of well-kept lawns, golf courses, parks, airports, and recreational fields, many of which have ponds and lakes nearby. The lakes, reservoirs, ponds, marshes, rivers, and streams in these areas are frequently dotted with islands which provide safe nesting sites and offer attractive habitat for geese. In addition, the traditional predators of geese (foxes, coyotes, etc.) are present in only low numbers or are absent in most urban areas. Hunting pressure from humans is also minimal in urban areas. The large body mass of western Canada geese, a common subspecies introduced in several states enables them to survive moderately cold climates and allows them to reside in an area year-around.

Unlike the migrant Canada geese that move north in the spring to nest in Canada and Alaska and south for the winter, resident geese spend the entire year in the local area. They prefer nesting on islands, and also may use structures such as nest boxes provided by humans, or they many simply nest on the ground. The typical Canada goose clutch averages five eggs and the geese incubate them for 25-30 days prior to hatching. The female incubates the eggs while the male vigorously defends her. Canada geese form strong pair bonds and pairs usually stay together year-round.

Determinations of absolute numbers for wildlife populations are frequently limited to educated guesses (Knowlton, 1972). However, waterfowl numbers are monitored more closely because they are considered game birds. Migratory Canada geese are highly mobile and their numbers vary seasonally. The term "resident" Canada goose refers primarily to local breeding Canada geese which nest and raise their young in the contiguous 48 states and migrate very little. Breeding bird surveys conducted annually in the U.S. have



shown an increasing significant trend ($P < .01$) for the Canada goose population from 1966 to 2001 (Sauer et al., 2002). As can be seen in figure 1.1 (Sauer et al., 2002), the resident Canada goose population in the U.S. started at less than one Canada goose/route in 1966 to over 20/route in 2001. A breeding bird survey route consists of 50 stops and surveys an area that is roughly equal to 10 square miles.

1.3.2 Damage Associated With Canada Geese

Comprehensive surveys of damage caused by Canada geese in the continental U.S. have not been conducted. However, WS operations obtain requests nationwide to resolve damage caused by Canada geese from property and resource owners or land managers who request WS assistance. In fiscal year 2001 (FY-01 - October 1, 2000 to September 30, 2001), WS operations received 4,238 requests for assistance with Canada geese in urban or developed environments for damage to property, natural resources, and the protection of human health and safety.

Property Damage. Property damage almost always involves an excessive amount of goose fecal matter that pollutes and contaminates landscaping and walkways, often at golf courses, marinas, and water front property. Damage can also occur when geese graze excessively on grasses and flower beds or pull grass plugs from golf greens in the summer. Businesses are also concerned about the negative aesthetic appearance of their property caused by excessive droppings and over-grazing, and are sensitive to comments by clients and guests. Costs associated with property damage include labor and disinfectants to clean and sanitize fecal droppings, implementation of non-lethal wildlife management methods, loss of property use, loss of aesthetic value of flowers, gardens, and lawns consumed by geese, loss of customers or visitors irritated by walking in or breathing the fumes of fecal droppings, repair of golf greens, and replacing grazed turf and landscaping.

Threats to Human Health and Safety. Threats to human health and safety include the threat from Canada goose strikes with aircraft, spread of pathogens or disease, attacks on humans, and others (WS, 1999; USFWS, 2002). Associated costs with human health and safety threats involving geese include testing of water for coliform bacteria, cleaning and sanitizing recreational areas regularly of fecal droppings, contacting and obtaining assistance from public health officials, implementing non-lethal wildlife management methods, missing connecting flights or departure and arrival times, etc. Aggressive territorial behavior exhibited by nesting geese can also result in children developing a fear of geese or other wildlife, personal injuries, and vehicle repairs.

Damage to Natural Resources. Natural resources include other wildlife, plants, and public recreational sites such as beaches and parks. In large concentrations, resident Canada geese create a reservoir for disease and may pose a health threat to migrating waterfowl. Tens of thousands of migratory waterfowl have been killed in single die-offs, with as many as 1,000 birds succumbing in 1 day (Friend and Franson, 1987). For this reason, the American Association of Wildlife Veterinarians (AAWV) put forth the following resolution:

"...the AAWV encourages local authorities and state and federal agencies to cooperate to limit the population of waterfowl on urban water areas to prevent disease outbreaks in semi-domestic as well as free-ranging ducks, geese and swans and discourages the practice of relocating nuisance or excess urban ducks, geese and swans to other parks or wildlife areas as a means of local population control".

Resident Canada geese also can cause extensive problems at public recreational sites where they defecate on trails, trample vegetation, and cause soil erosion. Excessive numbers of geese have also affected water quality around beaches and in wetlands by non-point source pollution and can remove shoreline vegetation resulting in erosion of the shoreline and soil sediments being carried by rainwater into lakes, ponds, and reservoirs. Geese have been reported to be sources of nutrients, elements such as nitrogen, and pathogens in water (i.e., coliform bacteria causes acidic pH levels in the water and lowers dissolved oxygen which kills aquatic organisms) (Cagle, 1998). Ecological damage to lakes from resident Canada geese has been documented since the early 1980's. Fecal matter from geese is a major source of phosphorus in lakes and can result in "phosphorus loading" of the lake. This enhances the formation of excessive algae blooms, which in turn caused depletion of dissolved oxygen in the deeper waters. This degradation of water quality reduces habitat for fish and invertebrates.

1.3.3 Canada Goose Damage Management Methods

The methods used by WS operations and the general public include a variety of techniques such as fencing, frightening devices (i.e. propane cannons, pyrotechnics, scarecrows), chase dogs, chemical repellents, alpha-chloralose (an immobilizing drug), drive-traps, live traps, and shooting. The NWRC has been extensively involved in the development and evolution of many of these methods, especially the use of repellents (Re-Jex-It) and immobilizing drugs (alpha-chloralose). A detailed discussion of these methods and techniques can be found in USDA, Appendix J (1997) and the DEIS (USFWS, 2002). Most Canada goose damage management methods have recognized strengths and weaknesses relative to each specific damage situation. WS operations personnel can determine for each damage problem and site what method or combination of methods is most appropriate and effective using the WS Decision Model (Slate et al., 1992). Other wildlife managers use similar methods to determine which tools are most likely to be effective for a particular situation.

Resource owner practices consist primarily of non-lethal preventive methods such as habitat alterations (i.e., tall grass management at an airport) and animal behavior modifications (i.e., pyrotechnics). Landowners can also potentially obtain permits to oil and/or addle eggs laid by Canada geese nesting on their property, depending on state wildlife policies and permit requirements in their area. In addition, some methods such as cage traps can be used non-lethally, often depending upon the circumstances. Canada geese captured with traps may or may not be relocated, usually it depends on social considerations such as hunting opportunities and aesthetics and the legality (some states do not allow resident Canada geese to be relocated). However, translocation of wild animals is discouraged by WS policy (WS Directive 2.501) because of stress to the relocated animal and poor survival rates due to intra-specific strife with established resident animals of the same species, and because of difficulties in adapting to new locations or habitats. Lethal control methods are often most appropriately used by people such as WS operations personnel trained and certified to use them. The public, in general, does not have the proper equipment, capability, access, or necessary training to use lethal techniques such as shooting in an urban area. The only fully lethal technique used for resident Canada geese is shooting. However, as stated above, many techniques (alpha-chloralose, live traps, drive traps, rocket nets, cannon nets, and hand capture) can be used lethally if the geese are euthanized following capture.

Nicarbazin would add another non-lethal tool to the techniques already in use. Research on this technique would provide confirmation as to the effectiveness of fertility control for Canada geese and would determine the applicability of such control to different damage scenarios.

1.4 SUMMARY OF PROPOSED ACTION

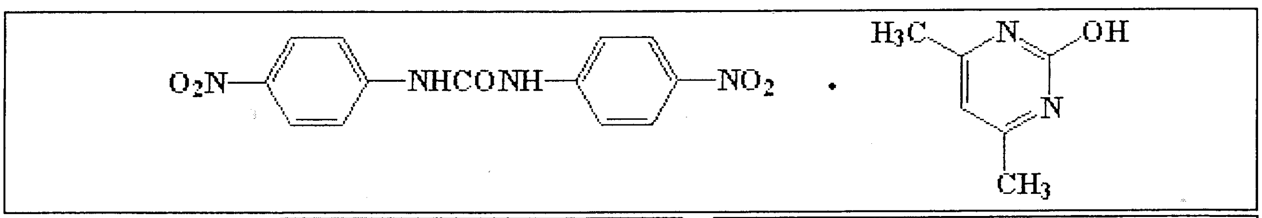
The Proposed Action is to conduct a field study on the effectiveness of nicarbazin baits as an oral infertility agent for resident Canada geese. Currently no infertility agents are approved for use for Canada geese and, as discussed, they are an ever-growing problem in the U.S. The field study will have 6 treated sites and 4 untreated sites to compare hatchability of eggs laid by resident Canada geese. The procedures of the study are given in detail in a protocol (Appendix B) prepared by the NWRC. NWRC and WS will obtain the necessary scientific collection permits to conduct the study from USFWS and the State of Oregon Department of Fish and Wildlife. [redacted] has approval from the U.S. Environmental Protection Agency (EPA) to conduct a large scale field efficacy study. The study will be conducted by WS operations personnel and coordinated/monitored by NWRC and [redacted]

Jones et al. (1990) demonstrated that from 25 to 100 ppm nicarbazin added to the diet of chickens (*Gallus domesticus*) reduced the hatchability of eggs produced from 6 to 10 days after treatment began. Hatchability of eggs produced by the 100 ppm treatment was reduced to <1 %. NWRC has been studying the use of nicarbazin and nicarbazin baits to control overabundant avian species since 1997. In a pilot study conducted in 1997, NWRC tested the effect of nicarbazin on Japanese quail (*Coturnix coturnix*) reproduction in the laboratory. The study demonstrated that 125 ppm nicarbazin was effective in reducing the hatchability of eggs to 0 % after 4 weeks, the first definitive demonstration in a species other than chickens (Miller, unpubl data, 2003). In 1999, studies at NWRC showed that Canada geese fed 125 ppm nicarbazin successfully absorbed it into the blood, although at a lower rate than seen in the chicken or mallard (*Anas platyrinchus*) (Miller, unpubl data, 2003). Another study (Yoder, unpubl data) conducted in 1999 indicated that nicarbazin baits containing from 125 to 500 ppm nicarbazin force fed to mallards resulted in hatchability rates of 0 to 15 % at the 500 ppm rate. Subsequent pen studies have shown that baits containing 500 ppm nicarbazin are effective in reducing the hatchability of eggs in mallards (Yoder, unpubl data, 2003) and Canada geese (VerCauteren, 2000). A field study in Nebraska (VerCauteren, 2000) showed that geese fed 500pm nicarbazin baits produced fewer eggs than expected and that hatchability was 0 %. In a multi-year field study in Colorado (Yoder, unpubl data, 2003) the use of nicarbazin baits in areas where Canada geese were nesting can effectively reduce the hatchability of eggs from 20 to 43%. Nicarbazin appears to be a promising avian infertility agent for use in controlling or maintaining resident Canada goose numbers.

NWRC and [redacted] have planned a nicarbazin field efficacy study for the spring of 2004 in Oregon to provide data for EPA registration of nicarbazin baits as an avian infertility agent. In the spring of 2003, NWRC and [redacted] personnel visited study sites to locate resident Canada goose nests to determine the suitability of potential sites for inclusion in the study. Sites in Oregon include corporate office complexes, golf courses, residential communities, and municipalities. More sites may be recruited to allow collection of additional data.

Nicarbazin. Nicarbazin is a 1:1 complex of two compounds, 4,4'-dinitrocarbanilide (DNC) and 2-hydroxy-4,6-dimethylpyrimidine (HDP), that exist as a crystalline complex. Once nicarbazin is ingested, the parent complex dissociates into DNC and HDP, releasing crystals of DNC ≤ 1 micron in size which allows for active transport of DNC from the gastrointestinal tract into the bloodstream. However, formation of small DNC crystals for uptake requires exposure to aqueous environment for several hours. DNC crystals are hydrophobic and quickly form aggregates greater than 1 micron in size, which are too large for active transport, if DNC is not in complex with HDP at the time of exposure to the aqueous environment. HDP protects DNC crystals from aggregation in an aqueous environment such as the gastrointestinal tract, which results in preservation of DNC crystals smaller than 1 micron in size for active transport into the bloodstream.

Structure of Nicarbazin



4,4'-dinitrocarbanilide (DNC) | 2-hydroxy-4,6-dimethylpyrimidine (HDP)

Nicarbazin has been registered with the Food and Drug Administration (FDA) for use in the poultry industry since 1955 to treat broiler (meat) chickens for coccidiosis, a sickness in chickens caused by intestinal protozoa. Coccidiosis in chickens results in diarrhea and general poor health, resulting in weight loss. Nicarbazin has been very effective in preventing coccidiosis, but it does not have any activity against bacteria. Fortunately, in the length of time that it has been used, coccidia strains have not developed resistance to nicarbazin. Nicarbazin is widely accepted and has been approved for use in all countries that raise broiler chickens as a very safe and effective product to prevent coccidiosis. A side effect has been found in the use of nicarbazin, a reduction in the hatchability of eggs laid by treated breeder or layer hens. For this reason, it was suspected that nicarbazin could provide a significant infertility effect for avian species.

Phibro Animal Health, INC markets the product Nicarb 25™ as its nicarbazin product to be used as a coccidiostat in chickens. Nicarb 25™ is 25% nicarbazin by weight coated onto wheat middlings, an inert carrier for the drug. Nicarbazin in its technical form (100%) is a very lightweight, highly electrostatic powder. Use of such a powder in feed mills processing feed into commercial chicken feed would result in a fine layer of nicarbazin dust deposited throughout the manufacturing area, potentially contaminating other feeds. Wheat middlings coated with nicarbazin results in a heavier less, electrostatic product, thus greatly reducing the risks of cross-contamination of equipment and feeds.

Ovistop® is a nicarbazin bait commercially available in Italy from the company Acme Drugs Spl. It is used to control reproduction in pigeons. Ovistop® is formulated as follows: 93.8% grain corn, 6.12% inerts, and 0.08% nicarbazin (800 ppm nicarbazin). Ovistop® has the appearance of a whole corn kernel coated with a waxy layer containing the nicarbazin. [redacted] has obtained the exclusive rights to market Ovistop® in the U.S. as the product [redacted] following EPA registration of the product.

The only other known adverse effect of nicarbazin in birds is an increased susceptibility to heat. In chickens, studies (Beers et al., 1989; Keshavarz and McDougald, 1981; Lee et al., 1994; Wiernusz and Teeter, 1995) have shown that treatment with nicarbazin reduces the bird's ability to dissipate heat when environmental temperatures and humidity are both high (over 90ºF and 85% humidity). In these situations, the chickens may overheat in a manner similar to heat stroke and death may result. Since resident Canada geese nest in the spring when the temperature and humidity conditions are usually not high enough to cause overheating, this side effect is not expected to be a concern.

Nicarbazin is thought to induce infertility in birds by two main mechanisms. Nicarbazin may disrupt the membrane surrounding the egg yolk, resulting in intermixing of egg yolk and white (albumin) components, creating conditions in which the embryo cannot develop. Nicarbazin may also inhibit incorporation of cholesterol into the yolk, a step that is necessary for yolk formation, thereby limiting energy for the developing embryo. If the yolk does not provide enough energy, the embryo will not completely form and the egg will never hatch. A third mechanism, which may only occur at very high doses of nicarbazin, is that the yolk may be significantly smaller than usual. If not enough yolk is deposited, the egg will not completely form inside the goose and components of the egg will be reabsorbed, resulting in no egg being laid.

1.5 RELATIONSHIP OF THIS EA TO OTHER ENVIRONMENTAL DOCUMENTS

1.5.1 WS Programmatic EIS. WS issued an FEIS (USDA, 1997) and Record of Decision on the USDA-APHIS-WS nationwide program. The FEIS discussed Canada goose damage management at the nationwide level and concluded that the nationwide WS program did not impact their populations. This EA is tiered to the FEIS and the pertinent portions of the FEIS that discuss NWRC research activities are incorporated by reference in this EA.

1.5.2 WS Operational Programs EAs. WS personnel in a number of states have prepared EAs for conducting resident Canada goose damage management (WS 1998, 1999, 2000a, b, 2002a, b, c, d, e). These EAs discuss the need for resident Canada goose damage management, issues, and impacts. All have reached a Finding of No Significant Impact (FONSI). These EAs are incorporated into this document by reference.

1.5.3. USFWS Draft EIS for Resident Canada Goose Management. A DEIS was issued by the USFWS (2002) with WS as a cooperating agency. The objective of the DEIS was to provide a regulatory mechanism to allow states and local agencies, other federal agencies, groups, and individuals to respond to nuisance complaints or damage caused by resident Canada geese. The DEIS analyzed alternatives that could reduce, manage, and control resident Canada goose populations to reduce damage. The DEIS is also incorporated into this document by reference.

1.6 DECISION TO BE MADE

Based on agency relationships, MOUs, and legislative authorities, WS is the lead agency for this EA, and therefore responsible for the scope, content, and decisions to be made. USFWS, the Oregon Department of Fish and Wildlife (ODFW), and the FDA have provided input for the study to facilitate an interdisciplinary approach in compliance with National Environmental Policy Act (NEPA), and agency mandates, policies, and regulations.

Based on the scope of this EA, the decisions to be made are:

- Should the field research on nicarbazin (Appendix B) be conducted?
- If not, what other potential control method should NWRC research to fulfill its congressional mandate?
- What mitigation measures should be implemented to reduce identified risks?
- Would the proposal have significant impacts requiring an EIS analysis?

1.7 SCOPE OF THIS EA ANALYSIS

1.7.1 Actions Analyzed. This EA evaluates a field study of nicarbazin for fertility control of existing resident Canada goose populations to protect property, natural resources, and human health and safety from resident Canada goose damage. This EA anticipates that should the study determine that the use of nicarbazin is an effective method, regulatory steps will be undertaken to authorize its use as an infertility agent under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

1.7.2 Period for which this EA is Valid. This EA will remain valid until WS completes the proposed study. If WS, NWRC, or [redacted] modifies the study such that it would have different environmental effects, a new EA will be completed or this EA would be supplemented pursuant to NEPA with the appropriate analyses.

1.7.3 Site Specificity. This EA analyzes potential impacts of nicarbazin as an anti-fertility agent for managing resident Canada goose populations. The study will be conducted at ten sites in Oregon. This EA emphasizes significant issues as they relate to specific areas whenever possible; however, the issues that pertain to resident Canada goose damage and management with nicarbazin are the same, for the most part, wherever they would be researched in Oregon, and are treated as such.

1.8 AUTHORITY AND COMPLIANCE

1.8.1 Authority of NWRC

WS Legislative Authority. USDA is directed by law and mandated by Congress to protect American agriculture and other resources from damage associated with wildlife. The primary statutory authority for USDA is the Act of March 2, 1931 (7 U.S.C. 426-426c; 46 Stat. 1468), as amended in the Fiscal Year 2001 Agriculture Appropriations Bill, which provides that:

"The Secretary of Agriculture may conduct a program of wildlife services with respect to injurious animal species and take any action the Secretary considers necessary in conducting the program. The Secretary shall administer the program in a manner consistent with all of the wildlife services authorities in effect on the day before the date of the enactment of the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2001."

U.S. Fish and Wildlife Service. USFWS has statutory authority to manage federally listed threatened and endangered (T&E) species through the Endangered Species Act of 1973 (ESA) (16 U.S.C. 1531-1543, 87 Stat. 884) and migratory birds under the Migratory Bird Treaty Act of 1918 (16 U. S. C. 703-711; 40 Stat. 755), as amended.

Oregon Department of Fish and Wildlife. ODFW has the responsibility to manage all protected and classified wildlife in Oregon including resident Canada geese, but not federally listed T&E species. A scientific collection permit application has been submitted to ODFW to obtain the appropriate state permit for this study.

U.S. Environmental Protection Agency. EPA's mission is to protect human health and to safeguard the natural environment. This mission includes the registration of pesticides in the U.S. Federal law requires that before selling or distributing a pesticide in the United States, a person or company must obtain a registration, or license from EPA. Before registering a new pesticide or granting a new use for a registered pesticide, EPA must first ensure that the pesticide, when used according to labels directions, can be used with a reasonable certainty of no harm to human health and without posing unreasonable to the environment. To make such determinations, EPA requires more than 100 different scientific studies and tests from applicants. Where pesticides may be used on food or feed crops, EPA also sets tolerances (maximum pesticide residue levels) for the amount of the pesticide that can legally remain in or on foods.

1.8.2 Compliance with other Federal Laws. Several federal laws regulate research conducted by federal entities. WS complies with these laws and consults and cooperates with other agencies as appropriate.

National Environmental Policy Act (NEPA). All federal actions are subject to NEPA (Public Law 91-190, 42 U.S.C. 4321 et seq.). NEPA sets forth the requirement for all major federal actions to be evaluated in terms of their potential significant impact on the quality of the human and natural environment for the purpose of avoiding or, where possible, minimizing significant adverse impacts. NEPA established the Council on Environmental Quality (CEQ) to oversee the federal government's responsibilities. Federal activities affecting the physical and biological environment are regulated in part by CEQ through regulations in Title 40 CFR, Parts 1500-1508. Each agency, such as APHIS, develops its own guidelines to comply with NEPA requirements. In accordance with CEQ and USDA regulations, APHIS Guidelines Concerning Implementation of NEPA Procedures, as published in the Federal Register (44CFR 50381-50384) provide guidance to APHIS/WS/NWRC regarding the NEPA process. WS follows the CEQ regulations implementing NEPA (40 CFR 1500 et seq.), USDA (7 CFR 1b), and the APHIS Implementing Guidelines (7 CFR 372) as a part of the decision-making process. These laws, regulations, and guidelines generally outline five broad types of activities that need to be accomplished as part of any project: scoping, analysis, documentation, implementation, and monitoring.

Endangered Species Act (ESA). It is federal policy, under ESA, that all federal agencies shall seek to conserve T&E species and shall utilize their authorities in furtherance of the purposes of the Act (Sec.2(c)). WS/NWRC conducts consultations with the USFWS, as required by Section 7 of the ESA, to utilize the expertise of the USFWS, to ensure that "*any action authorized, funded or carried out by such an agency . . . is not likely to jeopardize the continued existence of any endangered species or threatened species. . .*" (Sec.7(a)(2)). Mitigation measures from consultations are incorporated into EAs.

Migratory Bird Treaty Act of 1918 (16 U. S. C. 703-711; 40 Stat. 755), as amended. The Migratory Bird Treaty Act provides the USFWS regulatory authority to protect species of birds that migrate outside the U.S. Resident Canada geese are targeted in the proposed study, and a scientific collecting permit is required to conduct such activities.

Federal Insecticide, Fungicide and Rodenticide Act. The primary focus of The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) of 1947 was to provide federal control of pesticide distribution, sale, and use. In 1972, Congress passed the Federal Pesticide Control Act as an amendment to FIFRA. It is on this Act that most pesticide legislation is based. The central feature of FIFRA is its pesticide registration program, which requires all pesticides be registered with and approved by the EPA prior to manufacturing, marketing and distribution to ensure that the pesticide poses no serious threats to human health or the environment when used properly. Registration of new pesticides includes submitting to the EPA the pesticide's complete formula, a proposed label and a detailed description of the tests and results upon which the pesticide's manufacturer claims that the pesticide is an effective and safe method of controlling pests. A separate registration is required for each formulation. Each use of the pesticide must be supported by research documenting the environmental/health safety and effectiveness of the pesticide.

National Historical Preservation Act of 1966 as amended (NHPA). The NHPA and its implementing regulations (CFR 36, 800) require federal agencies to determine whether proposed activities constitute "undertakings" that can result in changes in the character or use of historic properties and, if so, evaluate the effects on historic and tribal cultural resources. Activities described under the proposed action do not cause major ground disturbance and are not undertakings as defined by the NHPA.

Environmental Justice and Executive Order 12898 - Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations. Environmental justice has been defined as the pursuit of equal justice and equal protection under the law for all environmental statutes and regulations without discrimination based on race, ethnicity, or socioeconomic status. Executive Order 12898 requires federal agencies to make environmental justice part of their mission, and to identify and address disproportionately high and adverse human health and environmental effects of federal programs, policies and activities on minority and low-income persons or populations. A critical goal of Executive Order 12898 is to improve the scientific basis for decision-making by conducting assessments that identify and prioritize environmental health risks and procedures for risk reduction. Environmental justice is a priority within USDA/APHIS/WS/NWRC. APHIS plans to implement Executive Order 12898 principally through its compliance with the provisions of NEPA.

WS activities are evaluated for their impact on the human environment and compliance with Executive Order 12898 to ensure Environmental Justice. NWRC personnel research and develop wildlife damage management methods as selectively and environmentally conscientiously as possible. All chemical means of animal control used by Wildlife Services operations are regulated either by EPA through FIFRA, or by the FDA through the Food, Drug and Cosmetics Act (FDCA). It is not anticipated that the proposed action would result in any adverse or disproportionate environmental impacts to minority and low-income persons or populations.

Protection of Children from Environmental Health and Safety Risks (Executive Order 13045). Children may suffer disproportionately from environmental health and safety risks for many reasons, including their development, and physical and mental status. Because WS makes it a high priority to identify and assess environmental health and safety risks that may have a disproportional affect children, WS has considered the impacts that this proposal might have on children. The proposed ARDM program would occur by using only legally available and approved methods where it is highly unlikely that children would be adversely affected. For these reasons, WS concludes that it would not create an environmental health or safety risk to children from implementing this proposed action.

1.9 A PREVIEW OF THE REMAINING CHAPTERS IN THIS EA

This EA is composed of five chapters and four appendices. Chapter 2 discusses and analyzes the issues and affected environment. Chapter 3 contains a description of each alternative, alternatives not considered in detail, and mitigation measures. Chapter 4 analyzes the environmental impacts associated with each alternative considered in detail. Chapter 5 contains the list of preparers of this EA. Appendix A is the literature cited and Appendix B is the Study Protocol. Appendix C contains summaries of environmental toxicity studies conducted with nicarbazin. Appendix D contains 2 summaries on nicarbazin compiled by the World Health Organization (WHO) and in conjunction with WHO.

CHAPTER 2: ISSUES

Chapter 2 contains a discussion of the issues, including those that will receive detailed environmental impacts analysis in Chapter 4 (Environmental Consequences), and those that were used to develop mitigation measures and standard operating procedures (SOPs). In addition, some issues arose that, with rationale, were not considered in detail. Pertinent portions of the affected environment will be included in this chapter in the discussion of issues used to develop mitigation measures. Additional information on affected environments will be incorporated into the discussion of the environmental impacts in Chapter 4.

Issues are concerns of the public or professional communities about potential environmental problems that might occur from a proposed federal action. Such issues must be considered in the NEPA decision-making process. Issues relating to the management of wildlife damage were raised during the scoping process in preparing the programmatic FEIS and were considered in the preparation of this EA. These issues are fully evaluated within the FEIS, which analyzed data specific to NWRC.

2.1 ISSUES CONSIDERED

Following are issues that have been identified as areas of concern requiring consideration in this EA.

- Effects on Target Resident Canada Goose Populations
- Effects on Non-target Egg-laying Species' Populations, Including T&E Species
- Effects of Nicarbazin on Public Safety

Potential environmental impacts of the Proposed Action and Alternatives in relation to these issues are discussed in Chapter 4. All issues, except the third, were addressed in detail in the FEIS. As part of this process, and as required by CEQ and APHIS NEPA implementing regulations, this document and its Decision are being made available to the public through "Notices of Availability" published in local media and through direct mailings of the Notice to parties that have specifically requested to be notified. New issues or alternatives raised after publication of public notices will be fully considered to determine whether the EA and its Decision should be revisited and, if appropriate, revised.

2.2 ISSUES USED TO DEVELOP MITIGATION

2.2.1 Effects on Non-target Egg-laying Species' Populations, Including T&E Species. A common concern among members of the public and wildlife professionals, including NWRC personnel, is the impact of chemical control methods and activities on non-target species, particularly T&E species. Nicarbazin is considered "practically nontoxic" to wildlife. The toxic effects of nicarbazin are discussed in Sections 2.3.1-3. Non-target birds and other small egg laying animals may be at some risk of reduced fertility due to ingesting nicarbazin treated bait. Data for most potentially impacted species is not available. However, published studies of the African house snake showed no effects on reproduction when dosed orally with nicarbazin at 200 mg/kg (Table 2.5). In addition, NWRC study procedures include measures intended to mitigate or reduce the effects of nicarbazin on non-target species. Special efforts are made to avoid jeopardizing T&E species through biological evaluations of potential effects and the establishment of special restrictions or mitigation measures. A description of mitigation measures established to avoid jeopardizing T&E and other potential non-target species are presented in Chapter 3 and analyzed in Chapter 4.

2.2.2 Effects of Nicarbazin on Public Safety. A formal risk assessment of the use of nicarbazin bait nationwide has not been conducted and will not be conducted until the results of this field efficacy study have been analyzed. However, this EA examines in detail the issues concerned with the specific proposed use in Oregon, discusses alternatives, and details mitigation measures to further reduce any potential effects of nicarbazin on wildlife, the public and pets. Mitigation measures to reduce risks to people and pets are given in Chapter 3 and analyzed in Chapter 4.

2.3 ISSUES NOT CONSIDERED IN DETAIL WITH RATIONALE

2.3.1 Toxicity of Nicarbazin to Non-target Animals. The public, regulatory agencies, and NWRC are concerned about the toxic effects of using chemicals in WDM on non-target wildlife and pets. Nicarbazin is considered practically non-toxic (LD_{50} >2,000 ppm) (tables 2.1 and 2.2). The concentration of nicarbazin in the proposed bait formulation is not expected to have a toxic effect on non-target wildlife or pets.

Birds and Mammals. Non-target birds and mammals could be directly exposed to nicarbazin by eating baits, or indirectly by eating geese that had consumed nicarbazin baits, or by eating goose feces containing nicarbazin or its metabolites. In the proposed field efficacy study, the concentration of nicarbazin in baits is 2,500 ppm or 0.25 %. The target dose for each resident Canada goose is 125 mg per goose per day during the application period, the amount of nicarbazin acquired by eating a total of 50 grams of nicarbazin bait each day (42-day treatment period). This concentration (2,500 ppm) is equal to 2.5 pounds of nicarbazin in every 1,000 lbs of bait.

The nicarbazin bait will be placed in bait stations and made available to geese from dawn to dusk, then removed over-night from each site. Goose activity and any other animals taking bait from the stations will be monitored by video cameras during times when bait is available. Many mammals, including rats (*Ratus norvegicus*), skunks (*Mephitis sp.*), raccoons (*Procon lotor*), coyotes (*Canis laterans*), and foxes (*Vulpes sp.*), that might eat nicarbazin baits feed primarily from dusk to dawn, so their exposure to the bait will be minimal. Dogs (*Canis domesticus*), squirrels (*Scirurs sp.*) and other small mammals that feed during the day may be exposed to the nicarbazin bait, but some male Canada geese will probably protect their food source and keep other animals away during much of the time that the baits are exposed.

Non-target birds such as starlings (*Sturnus vulgaris*), common grackles (*Quiscalus quiscula*), magpies (*Pica pica*), crows (*Corvus brachyrhynchos*), ravens (*Corvus corax*) and mallards (*Anas platyrhynchos*) may approach bait stations and consume some of the feed intended for the geese, however, consumption of bait should be limited by competition with the geese. Toxicity studies in birds and mammals given short- and long-term doses of nicarbazin have shown minimal effects because treatment levels that can cause toxicological effects are >>1,000 mg/kg on an acute basis or >>10,000 ppm on a sub-acute or chronic basis. Examples of known toxicity levels are shown in Table 2.1. For example, a rat would have to consume over 2.2 lbs of nicarbazin bait in a single feeding to have a 50% chance of dying. Extrapolated from chicken toxicity data (Table 2.1), a crow would have to consume approximately 1.4 lbs of nicarbazin bait each day for 84 days before it would have a 50% chance of dying .. The sheer volume of nicarbazin bait that would have to be consumed by a non-target birds and mammals precludes them from being affected by casual or regular exposure to nicarbazin baits. Adverse effects that have been noted in animals have generally been observed only after very long-term treatment of one year or longer. Long-term exposure such as that involved in chronic toxicity studies of target and non-target animals is not possible as the bait will only be offered 42 days.

Dogs, fox, coyotes and other urban predators could kill geese consuming nicarbazin baits, and a variety of urban scavenger species such as rats, skunks, raccoons, crows, ravens and magpies could consume the eggs, flesh or organs of geese that had been killed by predators. However, extrapolating from available dog toxicity data (Table 2.1), predators and scavengers are not expected to be at significant risk. Neither nicarbazin nor its components (DNC or HDP) bioaccumulate in geese. Assuming a worst case scenario where a 6.6 lb (3 kg) goose consumes 50 grams of bait per day, the maximum whole body nicarbazin residue per goose per day is about 41.7 ppm if none of the nicarbazin is metabolized or excreted in a 24-hour period. A predator or scavenger would need to eat over 40 geese (265 lbs) in a single day to reach the acute LD_{50} (>5000 ppm) for dogs, or over 13 geese (81 lbs) per day for 163 days to approach the chronic LD_{50} (>1600 ppm/day for 163 days). The concentration of nicarbazin or its components (DNC or HDP) in eggs is also unlikely to elicit any toxic effect since concentrations of these materials in eggs rarely exceeds 100 ppm.

Dogs, coyotes, and other mammals may occasionally consume goose feces. Again, these animals are not expected to be at significant risk. Based on the pervious scenario, but assuming 100% excretion of nicarbazin residues in feces, predators and scavengers would need to consume over 120 lbs of goose feces in a single day to reach the acute LD_{50} of nicarbazin. Similarly, they would need to consume more than 38 lbs of feces per day for 163 days reach the chronic LD_{50}. Consequently, there is little likelihood of mammals consuming enough feces to elicit a toxic response.

Fish and Invertebrates. Acute toxicity studies have been performed to determine the acute effects of the two components of nicarbazin, DNC and HDP, on water fleas (*Daphnia magna*), guppies (*Poecilia reticulate*), and rainbow trout (*Salmo gairdneri*) (Table 2.2). DNC is very insoluble in water, with a maximum water concentration of 20 micrograms/liter of water (0.02 ppm). This concentration of DNC in water, the highest possible, was not toxic to any of the species tested. HDP is much more soluble in water than DNC (56,000 ppm), and the minimal concentration that caused toxic effects on any species tested was 7.5 grams/liter of water (7,500 ppm). To reach this concentration of HDP in water would require that 86 lbs of nicarbazin bait be dissolved in a gallon of water, or that all the HDP be leached from 86 lbs of nicarbazin bait and concentrated in a gallon of water, neither of which is possible.

2.3.2 Effects of Nicarbazin on the Environment, including Soils, Water, and Plants. The public, regulatory agencies, WS, and NWRC personnel are concerned about the effects of using chemicals in WDM on the environment. Common concerns are centered on how WDM chemicals or drugs change or effect macronutrients in the soil, water quality, and plant growth and survival. All of these concerns have been addressed for nicarbazin.

Since nicarbazin baits will be offered in a bait station, the most likely route for nicarbazin to reach soil, water and plants is after it is digested and excreted by a goose. A secondary source would be from un-consumed baits that were removed from the bait stations and contacted water (i.e. rain, irrigation), dissolving the baits and leaching or depositing the nicarbazin from the bait into the soil. Once nicarbazin is consumed by an animal, dissolved in water, or deposited on the soil surface, nicarbazin separates into its components, DNC and HDP.

DNC very insoluble in water, is metabolized by the liver, and is eliminated slowly. Studies of nicarbazin have shown that DNC is undetectable in the plasma from 4 to 6 days after consumption; 9% is excreted by the kidneys and 85% is excreted unchanged in feces within 4 days (Appendix D). The remaining DNC is excreted in feces as a phenolic metabolite. HDP is rapidly cleared from the bloodstream by the kidneys. Twenty-four (24) hours after consumption, 90% of the HDP is eliminated as urea or uric acid and 10% is eliminated unchanged in the feces; no HDP residues form in the tissues. It is highly unlikely that enough nicarbazin, its components DNC or HDP, or its metabolites, could be excreted in goose feces to cause problems for plants, soils, or water. Some nicarbazin could also get into the environment through unconsumed bait. Radio-labeled nicarbazin studies have shown that the half-life of nicarbazin in the soil is approximately 49 weeks in field soil and 18 weeks in greenhouse soil (Appendix C). The shorter half-life in greenhouse soil is likely related to the higher temperatures and humidity maintained in the greenhouse study. Studies of radio-labeled nicarbazin in soil show that nicarbazin is incorporated into the upper 3 inches of soil and does not leach through the soil beyond 6 inches.

Chicken litter is routinely used as a fertilizer for agricultural fields and several studies have addressed the effect of nicarbazin in chicken litter on soil nutrient levels (Appendix C). Chicken litter includes urea and feces that contain DNC and HDP as well as nicarbazin-treated chicken feed spilled into the litter by the chickens. Chicken litter applied to agricultural fields at the standard rate of 12.5 tons/hectare (6.4 grams chicken litter/kilogram of soil) or ten times the standard rate (125 tons/hectare, 64 grams chicken litter/kilogram of soil) showed no significant differences in nitrate, nitrite, and ammonium levels in the soil compared to soil treated with chicken litter from untreated chickens. Likewise, there was no significant difference between soil treated with chicken litter from nicarbazin-treated chickens and with litter from untreated chickens in soil bacteria, actinomycetes, or fungi (Appendix C). Another study of the effects of chicken litter from chickens treated or not-treated with nicarbazin on total and methane gas production during anaerobic digestion in the soil showed that there were no differences, and that litter from nicarbazin-treated chickens was anaerobically digested similarly to litter from untreated chickens (Appendix C)

Nicarbazin levels 0, 1, 10, 100, and 1,000 milligrams/kilogram of soil were also studied to determine the effect of nicarbazin on the growth of oats, corn, tomato, lettuce, bean, turnip, pea, and sunflower (Appendix C). Nicarbazin was found to have no detectable effect on the long-term growth of any plants studied. No adverse effects were observed after seedling emergence and no adverse effects on fresh shoot weights between any of the treatment groups were noted.

The acute toxicity of DNC or HDP to unicellular algae (*Chlorella pyrenoidosa*) was also studied (Appendix C). HDP was tested at concentrations of 1, 2, 4, 8, and 10 grams/liter of water. DNC was tested at its maximum water concentration of 20 micrograms per liter of water. Concentrations of HDP that affected at least 50% of the algae were not reached even at the highest concentration tested, thus the EC_{50} of HDP for *C. pyrenoidos* is > 10,000 ppm. Similarly, the EC_{50} of DNC is > 0.02 ppm, which is the maximum concentration that could be tested.

2.3.3 Humaneness of Methods Used by WS and NWRC. The development and use of fertility control is considered a humane method for WDM and is a preferred method by many people and organizations to maintain animal populations at specific levels without having to resort to other methods of control. In addition, if contraception is being used, many methods considered inhumane by some people and organizations such as trapping, euthanization, and shooting would seldom be used. Thus, nicarbazin would be a beneficial tool in the area of humaneness. Therefore, this issue will not be discussed further.

2.3.4 Appropriateness of the Geographic Scope of the EA, Statewide. Federal agencies have the discretion to determine the geographic scope of their NEPA analyses [*Kleppe v. Sierra Club,* 427 U.S. 390, 414 (1976)] and WS has determined that preparation of this EA to address nicarbazin research in Oregon on private and other properties is appropriate. In terms of cumulative impacts, one EA covering Oregon is likely to provide a better analysis of impacts than multiple EAs covering individual sites within the analysis area. A more detailed and more site-specific level of analysis would not substantially improve the decision-making process, and pursuing a more site-specific and more detailed analysis might even be considered inconsistent with NEPA's emphasis on reducing unnecessary paperwork (Eccleston, 1995). If, in fact, a determination is made as a result of this EA that the proposed action would have a significant environmental impact, then an

EIS would be prepared.

2.3.5 Concerns That the Proposed Action May Be "Highly Controversial" and Its Effects May Be "Highly Uncertain", Both of Which Would Require That an EIS Be Prepared. The failure of any particular special interest group to agree with every act of a federal agency does not create a controversy, and NEPA does not require the courts to resolve disagreements among various scientists as to the methodology used by an agency to carry out its mission (Marsh v. Oregon Natural Resource Council, 490 U.S. 360, 378 (1989)). Although opposition may exist to nicarbazin research, this action is not highly controversial in terms of "size, nature, or effect." If a determination is made through this EA that the proposed action would have a significant environmental impact, then an EIS would be prepared.

2.3.6 Impact of Nicarbazin on Biodiversity. No WS wildlife management program or NWRC study has ever been directed toward the eradication of a native wildlife population. WS and NWRC operate in accordance with international, federal, and state laws and regulations enacted to ensure species variability. A reduction of a local group or population of Canada geese would normally be temporary because immigration or reproduction would soon replace the animals removed. For Canada geese, however, a reduction or stabilization of numbers that lasts for an extended period in a particular locale may be desirable and could possibly be achieved, over time, by the use of nicarbazin baits. This effect would be local in scope and would not cause significant regional changes in biodiversity.

2.3.7 Impacts of Limiting Canada Geese on the Public's Aesthetic Enjoyment. Wildlife is generally regarded as providing economic, recreational, and aesthetic benefits (Decker and Goff, 1987), and the knowledge that wildlife exists is a positive benefit to many people. Some members of the public have expressed concerns that Canada goose management could result in the loss of aesthetic benefits to the public, resource owners, or local residents from seeing Canada geese. Aesthetics is the philosophy dealing with the nature, or appreciation of beauty. However, aesthetics is subjective and highly dependent on what an individual regards as beautiful. The presence or absence of Canada geese could be considered as aesthetic for different individuals. In fact, cooperators in the research project have requested that the Canada geese be controlled and have cited aesthetics (i.e., goose feces on sidewalks, lawns, goose damage) as the primary reason for their decision to cooperate. The quantity of feces produced by geese and damage caused to grass and property often makes clean up and aesthetics a constant requirement of property owners.

Table 2.1 The Acute and Sub-Acute Toxicity of Nicarbazin to Birds and Mammals (Ott et al., 1956)

Species	Acute Nicarbazin LD_{50} (mg/kg)	2,500 ppm Nicarbazin BaitLD_{50} (lb/animal)	Maximum Dose Tolerated at Continuous Feeding
Chicken	2,400	2.47 (3.5 lb chicken)	1600 ppm for 84 days
Turkey	>2,400	>2.47 (3.5 lb turkey)	1000 ppm for 180 days
Mouse	>10,000	>0.22	Not Determined
Rat	>10,000	>2.20	1600 ppm for 177 days
Guinea Pig	>5,000	>0.29	Not Determined
Cat	>5,000	>14.00 (7 lb cat)	Not Determined
Dog	>5,000	>50.00 (25 lb dog)	1600 ppm for 163 days
Pig	Not Determined	Not Determined	10000 ppm for 49 days
Sheep	Not Determined	Not Determined	4000 ppm for 365 days
Calf	Not Determined	Not Determined	200 mg/kg body weight for 42 days

Table 2.2 The Acute Toxicity of Nicarbazin to Fish and Invertebrates

Species	DNC LC_{50} (ppm)	HDP LC_{50} (ppm)	HDP-Bait LC_{50} (lb/gal)	Reference
Water flea	>0.02[1]	7500	1260	Appendix C
Guppy	>0.02	7500	1260	Appendix C
Rainbow Trout	>0.02	7500	1260	Appendix C

[1] 0.02 ppm is the maximum solubility of DNC in aqueous solutions, thus the maximum concentration that could be tested.

Table 2.3 The Published Doses of Nicarbazin Tested in Various Bird Species

Species	**Proposed Use**	**Route Administered**	**Nicarbazin Dose Used**	**Effects, if any**	**Reference**
Chukar Partridge	Coccidiosis control	Oral	125 ppm in diet	Not effective for coccidiosis control	Ruff & Wilkins, 1989
Goslings (species not indicated)	Coccidiosis control	Oral for 14 to 21 days	145-280 ppm in diet	Not effective for coccidiosis control; no harmful effects noted on weight or in tissue histology	Perlstein et al., 1984
Japanese Quail	Coccidiosis control	Oral for 9 days	200 ppm in diet	Some control of coccidiosis; no toxicity noted	Dick and Ruff, 1982
Mulard (Muscovy X Pekin) Ducklings	Coccidiosis control	Oral for 14 to 21 days	145-280 ppm in diet	Not effective for coccidiosis control; no harmful effects noted on weight or in tissue histology	Perlstein et al., 1984
Muscovy Ducklings	Coccidiosis control	Oral for 14 to 21 days	145-280 ppm in diet	Not effective for coccidiosis control; no harmful effects noted on weight or in tissue histology	Perlstein et al., 1984
Ring-necked Pheasants	Coccidiosis control	Oral daily	125 ppm in diet	Not found to be effective against *Eimeria phasiani*; no toxicity noted	Sevcik et al., 1972
Ring-necked pheasants	Coccidiosis control	Oral daily for 11 days	125 ppm in diet	Ineffective in controlling coccidiosis; no toxicity noted	Ruff et al., 1992
Turkey	Effects on reproduction	Oral for 8-10 days	125 ppm in diet	Treatment for 7-8 days resulted in reduced hatchability of fertile eggs; embryonic mortality in first week of incubation; peak nicarbazin levels in blood reached 4 days after withdrawal from diet; 9 days post-treatment egg nicarbazin levels below embryotoxic level; 21 days post-treatment blood nicarbazin levels same as control	Jones et al., 1985
Turkey	Coccidiosis Control	Oral for 16 days	125 ppm in diet	Not most effective drug tested for coccidiosis control in turkeys	Edgar et al., 1961
Turkey	Coccidiosis control	Oral for 8 days	400-3200 mg/kg (0.03-0.16% in diet)	0.16% in feed required to completely inhibit oocysts; no toxicity noted in study; 0.8% nicarbazin in diet noted to slightly not significantly affect body weight	Cuckler et al., 1956

Table 2.4 The Published Doses of Nicarbazin Tested in Various Mammalian Species

Species	Proposed Use	Route Administered	Nicarbazin Dose Used	Effects, if any	Reference
Calves	Antihelminthic	Oral Drench	561 mg/kg	Very high doses used were toxic/lethal	Galvin et al., 1959
Calves	Coccidiostat for Eimeria bovis	Oral by capsule for 30 days; began 2 days before inoculation	1, 5, 7, 14, 25, 2g in gelatin capsules daily	Mid- to high-doses controlled coccidiosis; Toxicity noted at 25-27g daily as loss of appetite, reduction in weight gain, and in some cases lethal	Hammond et al., 1958
Calves (8-10 weeks old)	Study to isolate metabolite of nicarbazin	Oral for 4-6 weeks in milk as suspension	0.04, 0.2, or 1 g/kg	1 g/kg toxic and lethal; 0.2g/kg enlarged and damaged kidneys; both doses resulted in crystalline deposits in kidneys	Cuckler et al., 1956
Cattle	Study of potential drug absorption from feeding cattle chicken litter from chickens treated with nicarbazin	Oral for 121 days or 198 days	0, 25, or 50% broiler litter in diet with average nicarbazin concentration of 81.2 mg/kg litter	Nicarbazin detected in liver, muscle, kidney fat but levels were not significantly different from control animals and thus attributed to background interference in assays;	
Cattle	Study of potential contamination of milk from feed with nicarbazin	Oral for 3 weeks	1 to 12.5 mg/kg feed	No nicarbazin detected in any milk samples; very low nicarbazin levels found in fat after 8 days withdrawal	Kan et al., 2001
Mice	Treat toxoplasmosis infection	Oral by gavage	5mg daily beginning 4 days after inoculation	No effect on toxoplasmosis infection; no toxicity noted	Apt et al., 1978
Mice	Treatment of *Schistosoma mansoni* infection	Oral daily for 14 days to 18 weeks	0.2-1% in diet or 250 mg/kg for 10 doses in 14 days	All doses completely suppressed deposition of schistosome eggs but even 1% did not kill adult schistosomes; no toxicity was noted	Campbell & Cuckler, 1967
Mice	Suppression of deposition of eggs in *Schistosoma mansoni* infection	Oral for 2 weeks	0.1% and 0.4% in diet	Suppressed deposition of schistosome eggs, esp. at 0.4% level	Campbell & Rodgers, 1971
Mice	Treatment of *Schistosoma mansoni* and *Schistosoma japonica* infections	Oral for 5 weeks	0.3% in diet	Inhibits egg production by schistosome females; may cause delayed maturation and stunted growth of juvenile schistosomes	Reyes et al., 1975
Mice	Treat cryptosporidium infection	Oral daily beginning 4 days after inoculation	0.1 mg daily	No effect on cryptosporidium infection; no toxicity noted	Tzipori et al., 1982
Rabbits	Effect on intestinal digestion and absorption	Oral for 30 days	125 ppm in diet	No adverse effects on growth or feed intake; increased D-glucose and L-leucine transport through enterocyte plasma membranes with increased sucrase and aminopeptidase N enzyme activities	Sorribas et al., 1992
Swine	Antihelminthic	Oral	0.1% in diet	Prevented *Ascaris lumbricoides* infection	Cuckler et al., 1956

Table 2.5 The Published Doses of Nicarbazin in Various Other Species

Species	Proposed Use	Route Administered	Nicarbazin Dose Used	Effects, if any	Reference
African House Snake	Reproductive inhibition	Oral	200 mg/kg per female by gavage	No effects on reproduction; no toxicity noted	Mathies, 2000
Bowcutt Trout (Rainbow X Lahontan Cutthroat)	Control of Whirling Disease (*Myxosoma cerebralis*)	Oral in feed for 12 months	6-14 and 30-60 mg/kg in feed	Not effective in controlling whirling disease; no toxicity noted during study	Taylor et al., 1973
Earthworm	Toxicity Study	In soil for 14 days	0, 95, 171, 309, 556, and 1000 ppm nicarbazin in soil	No effects on body weight and no mortalities	Appendix C

CHAPTER 3: ALTERNATIVES INCLUDING THE PROPOSED ACTION

The FEIS developed 13 possible alternatives (USDA, 1997). However, the FEIS concentrated on the operations portion of WS. Research alternatives are typically limited to whether or not to conduct a study to meet the needs of the WS operations program and/or cooperators and stakeholders. WS operations, cooperators and stakeholders, including Congress, generally have requested or directed NWRC to develop new tools to manage wildlife and wildlife damage. Field research efforts are normally extensively studied in the laboratory and are not evaluated in the field until there is a reasonable amount of data available to indicate that the prospective tool will be safe and effective. In addition, a number of field studies are mandated by federal regulatory agencies before registration or authorization to use a particular material is granted. The proposed study is a field efficacy study required by EPA before approval for use of this compound can be granted.

Of the 13 possible courses of action, only two are relevant to this issue and are the standard alternatives for NEPA consideration, the "No Action" Alternative (do not conduct the study) and the "Proposed Action" Alternative (conduct the study). Other alternatives such as proposing different compounds or techniques to induce infertility have been, or are being investigated in the laboratory. However, there are currently no other options that are as biologically sound or cost-efficient as nicarbazin baits. The purpose of this study is to develop data for regulatory evaluation that will provide a new wildlife management tool . Wildlife managers may then evaluate and propose the best alternative for resolution of a particular wildlife problem in compliance with NEPA requirements.

3.1 ALTERNATIVES ANALYZED IN DETAIL

3.1.1 Alternative 1 - No Action - No Study. The No Action Alternative is the status quo. Under this Alternative, a research study on nicarbazin would not be conducted.

3.1.2 Alternative 2 - Proposed Action - Conduct the Study. This alternative consists of conducting a study to determine the effectiveness of nicarbazin baits as an infertility agent for selected groups or populations of rapidly increasing resident Canada geese in the U.S.

3.2 DESCRIPTION OF THE ALTERNATIVES

3.2.1 Alternative 1 - No Action- No Study. This alternative would consist of no WS or NWRC involvement in testing nicarbazin baits as an infertility agent for Canada geese. Private industry could perform these studies with, or without WS and NWRC involvement, perhaps without NEPA involvement. In addition, NWRC would have to research and develop other possible anti-fertility agents, techniques or methods to meet its congressional mandate to develop contraceptive and fertility control agents for several avian species. If this study could not be conducted, nicarbazin might be omitted from this list.

3.2.2 Alternative 1 - Proposed Action - Conduct the Study. This alternative would allow NWRC to go ahead with the nicarbazin field efficacy study for reducing the number of eggs that resident Canada geese hatch in a local area. Details of the study can be found in the study protocol in Appendix B. Only basic background information will be given here.

NWRC is planning a study for the spring of 2004 in Oregon to provide data for EPA registration of nicarbazin as an avian infertility agent. In the late winter and early spring of 2003, NWRC and [redacted] personnel visited study sites to locate Canada goose nests to determine the suitability of potential sites for inclusion in the study. They also held meetings at each proposed site to explain the study and to listen and respond to citizens, groups and government concerns, as well as private or public owners of affected lands.

Sites in Oregon currently include corporate office complexes, golf courses, residential communities, and municipalities. More sites may be recruited to allow collection of additional data. A total of ten sites will be selected, five from west of the Cascades and five east of the Cascades. Following NWRC field study protocol requirements, three sites in each area will receive nicarbazin-treated baits and two sites will receive untreated baits. Consumption of study baits will be monitored by video surveillance and by daily weighing of uneaten bait. Video cameras will also be used to monitor non-target animal activity at bait stations. In addition, nests of non-target birds will be monitored weekly to determine the status of eggs laid. In the event that a non-target nest is abandoned or eggs remain unhatched beyond the normal incubation period, eggs from the nest may be collected to determine fertility, and may be analyzed for nicarbazin residues. Goose nests at each study site will be monitored for egg hatchability, and sites will be compared to determine the effectiveness of nicarbazin in reducing hatchability.

The Oregon State WS Office will provide all personnel needed for the study. WS and other agency personnel are expected to be the end users of the product should it be registered. NWRC personnel will provide study coordination and oversight, and ultimately will collect and analyze the resulting data to prepare the submission to be sent to the EPA.

During the study, bait will be offered in black rubber feed pans (bait stations) that are approximately 5" tall and 11" in diameter. Bait stations will be placed in centralized locations in the areas where geese are nesting. This could include planters, landscaping, tall grass, shrubs and bushes, or on the lawn near the water source at the site (bait stations will be a minimum of five feet from water). WS personnel will work with the staff on site to select appropriate bait station locations and to minimize the appearance of the bait pans as needed. The study schedule will be adjusted such that feeding bait treated with nicarbazin would begin approximately 14 days before the peak of nesting of resident Canada geese in the area, which could be different at each site. Bait will be offered without restriction to geese and will be available from dawn to dusk. East of the Cascades, the study would begin in early- to mid-February and would end in late-April/early-May whereas West of the Cascades, the study would begin in mid- to late-February and would end in late-May/early-June. However, this schedule is dependent upon nesting activity. WS personnel will place bait at each bait station using a pre-determined route, and then will follow the same route again to observe feeding and other behaviors of the Canada geese at each site. Each bait station will be observed by WS personnel for approximately 15 minutes daily, which will result in WS personnel being at each site for several hours each day in order to monitor all of the bait stations at the site. In addition to WS personnel observations, bait stations will also be monitored remotely with video cameras. WS personnel will work with each facility to ensure that the Canada goose contraception study has a minimal effect on daily operations of the facility and management routines.

It is expected that each female Canada goose from each of the breeding pairs at each site will lay a clutch of eggs during the study. If the nicarbazin dose or the blood DNC levels are higher than expected, fewer eggs than normal may be laid by treated geese. Anticipated nicarbazin treatments will reduce the hatchability of eggs. Normal egg laying is a beneficial effect, as the goose will stay at the original nest and incubate the eggs rather than leaving the site and starting a new nest elsewhere. In egg oiling projects, Canada geese were reported to continue incubating a clutch of eggs for an average of 14 days beyond the expected hatching date if no eggs in the clutch hatched (Cummings et al., 1997).

This effect also reduced re-nesting. In previous nicarbazin field studies with Canada geese, incubation was also prolonged for an average of 14 days beyond the expected hatching date, which should also discourage re-nesting attempts. The time after which a goose will not re-nest appears to be based on several factors; how much energy the goose spent incubating the first clutch, daylight length, temperature, and activities of other members of the flock.

If nicarbazin baits are proven effective and approved for use by EPA, the product is intended to be used by wildlife managers from government agencies, municipalities, businesses, and private landowners for controlling resident goose populations. Use of nicarbazin bait would require the approval of appropriate federal, state, and local wildlife regulatory agencies and the supervision of a licensed veterinarian or trained wildlife manager.

3.3 ALTERNATIVES CONSIDERED BUT NOT ANALYZED IN DETAIL WITH RATIONALE

NWRC has been testing potential avian infertility agents for over thirty years. Many drugs and chemicals have been found to cause infertility in birds, but very few could be used safely without significant environmental or side affects. Some of these could provide alternatives to nicarbazin, but would have more significant adverse impacts on the environment and on other species that would have to be considered. NWRC has determined that nicarbazin should produce the best results with the least side effects. Other avian infertility agents for Canada geese are not being considered at this time.

The proposed study could be conducted at alternate sites. NWRC surveyed WS state offices to identify interest in participating in a field study. Oregon responded, noting they had a large number of complaints from urban/suburban areas that proved ideal for the proposed study. They were also willing to take part in a study. Therefore Oregon WS was selected to participate. If nicarbazin is shown to be effective in reducing Canada goose egg hatchability, [redacted] is expected to seek approval of nicarbazin baits for the entire U.S. and, therefore, use of the antifertility agent could eventually be expected to occur in urban/suburban settings throughout the U.S.

3.4 MITIGATION AND SOPs FOR WDM TECHNIQUES

Mitigation measures are any features of an action that serve to prevent, reduce, or compensate for impacts that otherwise might result from that action. The current WS nationwide program and NWRC follow many mitigation measures (USDA 1997, Chapter 5) to reduce or nullify impacts. Some key mitigating measures pertinent to the proposed action and alternatives that are incorporated into NWRC study procedures include the following.

- Conspicuous bilingual warning signs alerting people to the presence of nicarbazin treated baits will be placed at major access points to areas where baits are offered. Nicarbazin baits will only be placed where access to the public, especially children, can be limited.

- Research will be conducted by and overseen by trained professionals.

- Bait stations will be placed at least five feet from water to avoid the potential contamination.

- Bait stations will have bait placed in them from dawn to dusk. Bait not in use will be stored in a protected area at night with no animal access.

- Nicarbazin baits used for this study are of a size and type that is not preferred by most other species of birds, but are palatable to geese.

- WS operations on private lands are conducted with signed *cooperative agreements* which notify the landowner/manager of any possible risks.

- Reasonable and prudent alternatives and measures will be discussed through consultation with USFWS and may be implemented to avoid adverse impacts to T&E species.

- WS personnel will abide by all federal, state, and local laws while conducting this study. NWRC will obtain a Migratory Bird Collecting Permit from USFWS, and has applied for a scientific collection permit from the Oregon Department of Fish and Wildlife. [redacted] has already obtained EPA permission to conduct field efficacy testing of nicarbazin baits on geese.

CHAPTER 4: ENVIRONMENTAL CONSEQUENCES

Chapter 4 provides the information needed for making informed decisions in selecting the appropriate alternative for meeting the purpose of the proposed action. This chapter analyzes the environmental consequences of each alternative discussed in Chapter 3 in relation to the issues identified for detailed analysis in Chapter 2.

4.1 ENVIRONMENTAL CONSEQUENCES

This section analyzes the environmental consequences of each alternative in comparison with the proposed action to determine if the real or potential impacts are greater, lesser or the same.

4.1.1 Cumulative and Unavoidable Impacts. Cumulative and unavoidable impacts will be discussed in relationship to each of the potentially affected species analyzed in this chapter.

4.1.2 Nonsignificant Impacts. The following resource values within Oregon are not expected to be significantly impacted by any of the alternatives analyzed: soils and water (previously discussed in Section 2.3.2), geology, minerals, floodplains, visual resources, air quality, or prime and unique farmlands. Consequently, these resources do not require further analysis.

4.1.3 Irreversible and Irretrievable Commitments of Resources. No irreversible or irretrievable commitments of resources are expected, other than minor uses of fuels for motor vehicles and other similar materials. These will not be discussed further.

4.2 ISSUES ANALYZED IN DETAIL

4.2.1 Effects on Target Canada Goose Populations. NEPA requires federal agencies to determine whether their actions have a "significant impact on the quality of the human environment." A stable or declining population of an introduced resident wildlife species does not necessarily equate to a "significant impact" as defined by NEPA if the decline is collectively condoned or desired by the people that live in the affected human population. It is reasonable and proper to rely on the representative form of government within a state as the established mechanism for determining the "collective" desires or endorsements of the people of a state. NWRC and [redacted] abide by this philosophy and defer to the collective desires of the people of Oregon and the United Sates by complying with state and federal laws and regulations that govern the management, take or removal of wildlife. Although the analysis herein indicates that area-wide, state-wide or region-wide Canada goose populations are not being impacted to the point of causing a decline, if at some point in the future they are, then such a decline would not constitute a "significant" impact as defined by NEPA so long as the actions that cause the decline are in accordance with state and federal law, and concomitantly, with the collective desires of the people of the state.

4.2.1.1 Alternative 1 - No Action - No Study. Under this alternative, there would be no impact on target Canada goose populations in Oregon. However, WS and other wildlife management agencies and individuals could still provide the same level of direct control at the ten sites chosen for the study that have been provided in the past, depending on the severity of the local problem, some of these methods could impact individual Canada goose populations, however, it is unlikely that the overall Canada goose population would be impacted because population trends based on Breeding Bird Survey data indicate that the Western BBS Region and the U.S. (Fig. 1-1) are having significant increases in Canada geese, increasing from less than 1 goose per survey route in 1966 to over 20 in 2001 nationwide. Oregon had a non-significant trend. In urban areas where the resident goose populations have been increasing significantly, many people would like to see their populations managed to maintain more agreeable numbers. Without this study, another contraceptive or infertility agent (in addition to egg addling and egg oiling) would be unavailable to keep a resident population from increasing beyond what is acceptable to the majority of the public and property owners. On the other hand, some people who enjoy the overabundance of geese may not want the goose population static.

4.2.1.2 Alternative 2 - Proposed Action - Conduct the Study. Under this alternative, WS would treat six sites with nicarbazin baits to produce infertility in resident Canada geese. Sites will be used that have at least ten breeding pairs of Canada geese. It is very difficult to administer exact doses of nicarbazin under free-feeding conditions such as those that will be used in this study. However, nicarbazin has been shown to have a wide margin of safety under free-feeding conditions. Studies have indicated that the average Canada goose eats a little under 4 ounces dry-weight (90-100 grams) of food per day (Nagy, 1987). The nicarbazin bait is formulated so that a target dose of 26.67 mg/kg/day is administered in about 4 ounces (100 grams) of bait. It is unlikely that a single goose could consume more than 6 ounces (150 grams) of nicarbazin bait in a day (3 times higher than our target dose) due to the size and physiology of the gastrointestinal tract, feeding habits of geese while nesting and preferences for other food (grass). The passage of food in the intestinal tract of a goose from the time of ingestion to the time of excretion is approximately 30 to 90 minutes, which is a factor that must be considered as well (Mattocks, 1971). Only a portion of the nicarbazin will be absorbed in the gut before the rest was excreted. In the event that a goose did consume more than the anticipated dose of nicarbazin, it would not produce any toxic effects, but the blood levels of nicarbazin (DNC and HDP) would be increased and absorption of the nicarbazin in the yolk of the egg would also be increased.

The ideal situation would be that each goose in the study consumes 50 grams of bait each day. WS personnel will provide bait daily during the study to maximize the chances of the Canada geese in the study getting their daily dose of nicarbazin. There appears to be a threshold level of DNC in the blood required to affect hatchability of the eggs formed during that time period. If a goose doesn't eat the bait for a day or two, it is likely that the DNC levels in the blood will fall and may fall below the level required to affect hatchability. The DNC levels in the blood will rise again when the goose consumes more bait, and the eggs formed during the time when the DNC levels are high again would be affected and would not hatch. A single clutch may have eggs with high DNC levels and eggs with low or undetectable DNC levels, all of which is dependent on how much bait the goose consumed and what the blood DNC levels were while the egg was forming. In some cases, a few of the eggs may hatch with normal goslings and few eggs may not hatch.

If this study is effective and all breeding pairs produced no goslings, the maximum of goslings that would not be produced statewide would be 900 (*sic sites with 30 breeding pairs averaging five goslings per clutch*). However, it is more likely that some goslings will be produced, but at a significantly lower rate than at untreated sites. To determine the effectiveness of the treatment, the number of eggs produced that hatch (hatchability) at treated sites versus untreated sites will be compared. This measure will also allow a precise estimate of egg production decrease, if any. If breeding pairs re-nest (as discussed in Section 3.2.2) successfully it could increase the number of goslings produced, but this is a time-limited study and these data may not be captured.

The significance of not producing 900 goslings can be compared with the Canada goose population in Oregon. The Oregon breeding population of Canada geese averaged about 53,000 from 1994 to 1998 (USFWS, 2002), thus not producing 900 goslings could reduce the initial population gain from all breeding pairs in 2004 by less than 1%. This would be a minimal level of take and not significant to the overall population. Additionally, the DEIS (USFWS, 2002) discusses the management of resident Canada geese in the U.S. and in many instances local goose populations have far surpassed the level of tolerance. Therefore, we conclude that the nicarbazin field study will not significantly impact Canada goose populations in Oregon. The goal of many property owners that are cooperators in this study, and others, is to see reduced hatchability of eggs produced by resident populations or to see reduced levels of damage caused by resident Canada geese.

4.2.2 Effects on Non-target Egg-laying Species' Populations, Including T&E Species

4.2.2.1 Alternative 1 - No Action - No Study. Egg-laying non-target birds, reptiles, amphibians, fish, and invertebrates, including T&E species, would not be affected by any activities of NWRC or WS since the study would not be conducted. However, considering the growth of Canada geese, degraded water quality where goose populations are excessive could negatively impact fish and aquatic invertebrates. Excessive numbers of waterfowl have been reported to be sources of nutrients, elements such as nitrogen, and pathogens in water (i.e., coliform bacteria causes acidic pH levels in the water and lowers dissolved oxygen which kills aquatic organisms) (Cagle, 1998). For example, ecological damage to Lake Ballinger in Washington from resident Canada geese has been documented since the early 1980's (WDOE, 1999). Phosphorus loading from fecal matter has been a serious ecological concern in the Puget Sound area as well as many areas in the U.S. Fecal matter from geese has been found to be a major source of "phosphorus loading" in some lakes. This enhanced the formation of excessive algae blooms, and in turn caused depletion of dissolved oxygen in the deeper waters. This degradation of water quality reduced habitat for fish and invertebrates and further enhanced the recycling of phosphorus from the bottom sediments.

Overall, not conducting research on new potential WDM tools for managing Canada geese may not provide wildlife managers with enough options to control problems. This could actually enhance the degradation of water quality and other habitats, and adversely impact aquatic species. For example an average 10 lb goose defecates between 5.2 and 8.8 times per hour (Bedard and Gauthier, 1986), and produces approximately 3 pounds of feces every day (USFWS, 1998). Kear (1963 *In* Allan et al., 1995) recorded a maximum fecal deposition rate for Canada geese of 0.39 pounds per day (dry weight).

If the study were completely successful, there would be an estimated 900 fewer goslings produced at the treatment sites (Section 4.2.2.1). More conservatively, if the nicarbazin treatment were only 50% successful, then 450 fewer goslings would be produce. Assuming the average goose deposits about a third of the daily maximum, or 0.13 lbs of feces (dry weight)/day, and assuming no mortality; there would be a reduction of 21,353 pounds of feces per year. This could have a substantial effect on water quality at sites were runoff into water bodies is a concern.

4.2.2.2 Alternative 2 - Proposed Action - Conduct the Study. Under Alternative 2, nicarbazin baits would be placed in bait stations at six sites in urban and suburban settings in Oregon. It is possible that other egg-laying species such as birds, reptiles, amphibians, fish, and invertebrates, could feed on the baits, which could reduce their egg-laying potential. The nicarbazin bait used in this study has been designed to limit non-target animal consumption with the size of the baits preventing songbirds and other small birds from eating the baits. Since Canada geese will typically aggressively protect their food sources, they are expected to chase away other birds attempting to eat the bait offered.

Canada geese typically nest earlier in the year than most other waterfowl species that would consume the bait and before many songbirds. Nicarbazin bait will be offered as early as February and will end in early April. Nicarbazin bait must be consumed for several days to achieve blood levels that affect the hatchability of eggs that are forming. Nicarbazin is undetectable in the plasma of Canada geese, mallards, and chickens by 4-6 days after consumption of nicarbazin bait has stopped. The levels of DNC in the blood are reduced by half within one day after bait consumption stops. If the level of DNC falls by approximately one half its peak levels, the effect on the egg being formed has almost disappeared. By two days after bait consumption has stopped, no effects on the egg being formed are seen. Since most waterfowl do not begin to nest until at least May, no effects on the hatchability of eggs of non-target waterfowl that do consume bait are expected as bait exposure will stop before their nesting season is beginning.

Nicarbazin baits are to be used at sites, office complexes, golf courses, residential communities, and municipalities, which are not as conducive to attracting many species of egg-laying animals that could consume the bait. These areas are also places where T&E species are typically not found. Birds in urban and suburban type habitat are typically common species because they have adapted to the presence of man. In, Oregon, only a few other species are expected to consume the baits, primarily mallards, domestic waterfowl, and possibly gulls, crows, and pigeons. However, because much of this consumption is expected to be occasional or intermittent, nicarbazin is not expected to have any significant impact on these species.

Studies of the effects of nicarbazin on animals other than birds that lay eggs have been limited to snakes. When brown tree snakes were treated with nicarbazin, the number of eggs laid, the hatchability of the eggs, and the health of the offspring were not affected by treatment. It is possible, but not probable, that other egg-laying species, such as turtles, could feed on the bait. We conclude this risk is very minimal, but will monitor bait stations with video cameras and observers to determine if a site has non-target species feeding on the bait. Bait stations will be moved if non-target species are found frequenting the site and consuming bait. A list of current T&E species was obtained May 28, 2003 from the USFWS Ecological Service Office in Portland, Oregon. We have determined that the proposed study will have "no effect" on T&E species in Oregon.

4.2.3 Effects of Nicarbazin on Public Safety

4.2.3.1 Alternative 1 - No Action - No Study. Under this alternative, there would be no effect on the public other than the problems associated with increasing geese populations. If under this alternative, nicarbazin baits were not placed there would be no potential for human exposure to nicarbazin. Although the resident goose populations are growing, and habitat degradation and several diseases are associated with them, we believe that there would be no significant short-term effect on public safety under this alternative. However certain other nuisance and esthetic issues would remain, including potential negative impacts on property and natural resource.

4.2.3.2 Alternative 2 - Proposed Action - Conduct the Study. Under this alternative, nicarbazin baits would be placed out at six sites in urban and suburban areas where the public could potentially be in contact with bait. During the study, NWRC will place bait stations in areas where children are not likely to have access to the nicarbazin bait. Ideal locations for bait stations include islands in rivers or ponds, in taller grasses and areas with brush and bushes, and areas fenced off to prevent easy access by humans. Signs or posters informing people of the study will be posted at various locations around the study site to increase awareness of the presence of the nicarbazin bait.

No adverse effects are expected in children or adults due to nicarbazin consumption. The untreated bait is bland tasting and neutral in color. Thus it has no particular appeal. In fact, the treated bait has a mild astringent quality and would cause a "cotton-mouth" feeling and would provide a negative stimulus that would discourage further consumption. The baits are approximately 3/8 inch in diameter and should pose little choking hazard to children.

The FDA has a rigorous evaluation system to determine the human food safety of any product used in food. Nicarbazin is already FDA-approved for use in broiler (meat) chickens as a coccidiostat to prevent disease and has a long history of safety. It has been determined that nicarbazin is safe in chicken meat at a level of 4 milligrams per kilogram with a human consumption of 1 pound (500 grams) of meat per day by a 120 pound (60 kilogram) human over a lifetime (U.S. Department of Health and Human Services, Public Health Service, FDA, Center for Veterinary Medicine Guidance Document Guideline No. 3. General Principles for Evaluating the Safety of compounds Used in Food-Producing Animals Part IV. Guideline For Establishing A Tolerance changed to Guideline For Establishing A Safe Concentration; Code of Federal Regulations, Title 26, Volume

6, Parts 500 to 599, 2003; Code of Federal Regulations, Title 21, Volume 6, 2003). It is not anticipated that humans will consume geese treated with nicarbazin prior to the hunting season in the fall, which is well beyond the FDA recommended 4-day withdrawal period for treatment of chickens with nicarbazin. However, there is a slight chance that a treated goose could be illegally consumed by a human during or immediately following treatment with nicarbazin bait during the study. Based on calculated lifetime exposures, no effect on humans consuming meat with nicarbazin residues is expected even if meat is consumed prior to the 4-day withdrawal period.

Another potential impact would be the illegal or wrongful use of nicarbazin. Because this is a research study, access to and use of the nicarbazin baits are tightly controlled. No unauthorized persons will be allowed to access treated baits.

We believe that development of this compound as a non-lethal infertility agent for resident Canada geese will be positive and will provide more options for wildlife management personnel. This alternative would likely be more beneficial than Alternative 1.

4.3 ALTERNATIVE IMPACTS

Each of the 2 analyzed alternatives would have varying impacts under the 3 issue areas, but for the most part, would be fairly similar. Alternative 2 would probably have the overall lowest impacts on the environment (Table 4-1) if nicarbazin baits were found to be effective at controlling resident Canada goose numbers because reduced hatchability of eggs laid by resident Canada geese at some sites could have a profound positive benefit.

Table 4-1. Alternative Impacts on Issues Compared.

Issues	Alternative 1	Alternative 2
Target Species	None	None
Non-target Sp. Pops.	Slight Negative to None	Minimal to Slight Positive
-T&E Species	Slight Negative to None	Minimal to Slight Positive
Public Safety	Negative to None	Slight Negative to Positive

CHAPTER 5: LIST OF PREPARERS AND PERSONS CONSULTED

5.1 List of Preparers

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5.2 List of Persons and Agencies Consulted

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- William Erickson, OPP, EFED (protocol review)

U.S. Fish and Wildlife Service, Region 1

- Brad Bortner, Chief, Division of Migratory Birds and Habitat Programs

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- Bradley Bales, Staff Biologist, Game Bird Management, Wildlife Division

APPENDIX A

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National Wildlife Research Center
Wildlife Services
Animal and Plant Health Inspection Service
United States Department of Agriculture

Study Protocol

1. Title:
Multi-center Field Study of Nicarbazin Bait for use in the Reduction in Hatching of Eggs Laid by Local Canada Goose (*Branta canadensis*) Flocks

2. Study Director:
Kimberly S. Bynum

3. Sponsor:
Name: USDA/APHIS/WS National Wildlife Research Center
Product Development Program
Address: 4101 LaPorte Avenue
Fort Collins, CO 80521

Co-Sponsor of the study: Name: [redacted]
Address:

4. Testing Facility:
The study will be coordinated from the National Wildlife Research Center, Fort Collins, CO. However, the study will be conducted at up to 12 field sites throughout Oregon. Agreements have been or will be obtained from the managing authority at each study site to conduct work at the field sites. The final selection of study sites will occur in February or March 2004 and will be based on the presence of adequate numbers of geese. The study will be conducted in Oregon, utilizing the differences in the climate and habitat east and west of the Cascade Mountains as two distinct geographic areas of the United States. The following locations are being considered for inclusion in this study.

Location	City	County
[redacted]		Multnomah County
		Deschutes County
		Jefferson County
		Lake County
		Washington County
		Wasco County
		Lane County
		Lincoln County
		Linn County
		Wasco County
		Jefferson County
		Columbia County
		Multnomah County

Additional sites may be considered if inadequate numbers of geese are present at these sites.

5. Background and Justification:
As goose populations and urban areas expand and overlap, Canada geese are more often considered a nuisance and potential health problem (fouling land and water, colliding with and damaging aircraft, etc.). Non-lethal and humane means of managing the size of Canada goose flocks residing near or on airports, golf courses, industrial parks, government sites, city parks, etc. are needed. Nicarbazin is approved for use as a coccidiostat in broiler chicken feeds.

Nicarbazin has been used for many decades to control coccidiosis in broiler chicken production. Accidental feeding of nicarbazin in layer/breeder chickens resulted in a decrease in egg production and hatch. One hypothesis on the mechanism by which nicarbazin exerts its effect (reduced the hatchability of eggs) is by causing disruption of the vitelline (yolk) membrane allowing the yolk and albumin to intermix, creating conditions under which the embryo cannot develop. While this effect is detrimental to chicken production, it has the potential to be useful as a fertility control agent for managing wild bird populations (i.e. geese).

[redacted] (in collaboration with the National Wildlife Research Center) is developing a nicarbazin goose bait product intended for use as a tool in the management of local Canada goose populations by reducing egg hatching. This product will be offered to resident geese in flocks frequenting designated sites to deliver the nicarbazin active ingredient. Nicarbazin bait offered to specific Canada goose populations will be regulated through United States Fish and Wildlife Service and state wildlife agency scientific collection and research permits as Canada geese are a species protected by the Migratory Bird Act.

The information obtained in this study will be used to support the effectiveness of nicarbazin under the product's proposed conditions of use to reduce hatching of eggs laid by resident Canada goose flocks.

6. Objectives/Hypotheses:
The hypothesis of this study is that daily baiting of resident Canada Geese immediately prior to and during breeding season will reduce the hatachability of eggs, thereby reducing the number of chicks being introduced into resident goose populations.

The primary objective of this study is to determine the effectiveness of [redacted] Nicarbazin based goose bait [redacted] for reducing hatching rate in eggs laid by breeding pairs in resident Canada goose (*Branta canadensis*). A secondary objective of this study is to determine the potential impact of a nicarbazin baiting program on locally occurring non-target species.

7. NWRC Approved Project Title:
This project will be conducted under the Avian Infertility Project led by Lowell Miller.

8. Regulatory Compliance/Guidelines:

Regulatory Standard: Check as appropriate.

	None, non-regulated study
X	CFR Title 40, Part 160: Good Laboratory Practice Standards (FIFRA);
	CFR Title 21, Part 58: GLP Standards for Nonclinical Laboratory Studies, (FFDCA)
	Other:

9. Study Classification Information

Does this study include any or all of the following? Check as appropriate.

X	Animals -- please complete and attach Animal Use Appendix
	Plants -- no additional appendix required
	Microbiological/Biohazardous Materials - please complete and attach Microbiological/Biohazardous Materials Use Appendix
	Chemical Analysis -- please complete and attach Analytical Chemistry Appendix
	Literature review only -- no additional appendix required
	Statistical or economic analysis only -- no additional appendix required
X	Use of a test, control, references substance, bait or device -- complete and attach Test, Control and Reference Materials/Device Formulation and Use Appendix

10. Methods/Procedures:

<u>Definitions</u>

Adverse Event:
An undesirable event or finding noted during the course of the study, including study animals in poor health, injured study animals, death of study animals, etc. to be reported to the study director immediately upon discovery.

Bait: Generic term referring to feed offered to geese for consumption.

Baiting Strategy:
The daily routine used to apply and retrieve bait at each site, including the amounts of bait offered, the route taken to apply bait, etc.

Bait Station: Black rubber feed pan into which bait is offered to geese for consumption and an area 5 feet in diameter around the bait-feed pan.

Breeding Pair: A male and female Canada goose that mate and nest, ultimately resulting in egg production by the female.

Clutch: A nest of eggs; the experimental sub-unit.

Control Bait: Bait without nicarbazin to be used during Treatment period, synonymous to 'Untreated Bait.'

Estimated Hatching Date:
: Approximately 28 days from the date on which the last egg in a clutch is laid.

Field Coordinator:
: Person acting to support the Investigator by assisting in coordinating supplies and solving problems on-site during the conduct of the field study.

Field Personnel:
: People within each geographic area responsible for actual conduct of the study at one or more study sites.

Flock: A group of Canada geese feeding and nesting together; the experimental unit.

Geographic Area:
: Area of the United States that contains at least 5 study sites; areas to be designated as east or west of the Cascade Mountains with each area having distinct differences in climate and habitat.

Investigator: Person that will coordinate study activities at the study sites.

Non-target Species:
: Any species other than the Canada goose.

Sponsor Representative:
: Person to be contacted to represent the Sponsors.

Standard Operating Procedure (SOP):
: Procedure by which a standard event/operation should be carried out.

Study Director:
: Person to be contacted regarding conduct of and data collection for the study.

Study Site: Location where a flock of Canada geese nests.

Treated Bait: Bait with nicarbazin to be used during Treatment period.

Test Bait: Bait to be used during Treatment period (same as treated bait).

Untreated Bait:
: Bait without nicarbazin to be used during the Acclimation period, synonymous with 'Control Bait.'

<u>Treatment Groups</u>

Group	No. Flocks /Region [a]	TREATMENT				
		Bait Type [b]	Dosage [c]	Route	Frequency [d]	Duration [e]
A	2	Control	25 g of bait/goose (0 ppm)	Oral	Daily	Approximately 42 days
B	3	Treated	25 g of bait/goose (up to 2500 ppm)	Oral	Daily	Approximately 42 days

[a] Five flocks from each of two geographically distinct regions of the U.S. will be enrolled in the study. The two distinct geographic regions will be in Oregon, either east of the Cascades or west of the Cascades.

[b] Control bait is a bait formulation manufactured without nicarbazin.
Treated bait is a bait formulation manufactured with nicarbazin.

[c] Target dosage is 25 grams of bait per bird per day (for treated bait at maximum concentration of 2500 ppm nicarbazin, approximately 15.625 mg nicarbazin per kg body weight per day, an average of 62.5 mg nicarbazin per 4 kilogram goose per day).

[d] Bait provided once daily dawn to dusk.

[e] Drug will be withdrawn after approximately 42 days of treatment.

Schedule of Events

Approximate Study Day	Activities
Approx. Day –50 to –20 **Personnel Training**	• Training of Investigators and Field Personnel (study procedures, SOPs, GLP, etc.) • Training at individual sites
Approx. Day –14 to –7 **Acclimation Period Phase I**	• Provide ***untreated bait*** daily and develop baiting strategy • Flock counts every third day • Operate bait station video monitoring stations for non-target species observations
Study Day –7 to –1 **Acclimation Period Phase II**	• Provide pre-weighed ***untreated bait*** daily and optimize baiting strategy • Flock counts daily • Record weight of uneaten bait daily • Record abnormal health observations daily • Record pairing activity observations daily • Stratify and randomly assign flocks to treatment group. • Obtain appropriate bait for each site as determined by treatment group assignment. • Operate bait station video monitoring stations for non-target species observations
Day 0 to 30 **Pre-Nesting Treatment Period**	• Provide pre-weighed bait (control or test) daily (amount based on consumption during acclimation period) beginning (around March 1st) approximately 14 days before the first egg is expected • Record weight of uneaten bait daily • Calculate bait consumption • Flock counts daily • Find and count nests daily once nesting begins • Egg counts for each nest every other day until day 23 of incubation, daily therafter • Record abnormal health observations daily • Record pairing and nesting activity observations daily • Operate bait station video monitoring stations for non-target species observations
Day 31 to 42 **Nesting Treatment Period**	• Provide pre-weighed bait daily • Record weight of uneaten bait daily • Calculate bait consumption • Flock counts daily • Nest counts daily • Egg counts for each nest daily • Record abnormal health observations daily • Record pairing and nesting activity observations daily • Operate bait station video monitoring stations for non-target species observations
Day 43 to 79 **Gosling Hatching Period**	• Flock counts daily • Nest counts daily • Egg counts for each nest every other day until day 23 of incubation (five days prior to estimated hatching date) and then daily until hatching or abandonment of nest • Record abnormal health observations daily • Record brood counts and egg hatching observations daily
Day 85 **Study Ends**	• ***Discontinue monitoring***

Description of Field Procedures

Study Site Selection

Consideration will be given to the following criteria when enlisting the Investigators and flocks:

- Limited access - Sites should have minimal human/dog contact (for example private golf courses, industrial parks, government controlled areas, etc.).
- Established flock - Flock should have been in place for at least three years with goslings present on the site in the previous year. The flock should have at least 10 potential breeding pairs.

- Nesting - Birds should have food sources and be eating within relatively close proximity of the nesting area (geese tend to use the same nests from year to year).
- Feeding - Potential feeding/baiting areas should be available with limited access to humans, domestic animals or other wildlife.
- Distance between Study Sites - Sites will be a distance of at least 10 miles apart to minimize risks of intermingling of flock members between sites.

Flock Inclusion Criteria

To be eligible for participation in the study, ALL of the following criteria must be met:

- The flock must conform to the test animal (flock) description.
- The flock must be manageable and cooperative with study procedures (accliminated to consume test bait from bait stations).
- There must be at least 10 potential breeding pairs at the site.
- The flock must be located at a site suitable for the study, which includes having easy access to nest sites.
- Locations of study sites utilized by flocks will be a minimum of 10 miles apart to minimize intermingling of geese between study sites.
- The flock must be considered a "resident" flock which does not migrate.

Flock Exclusion Criteria

A flock will be ineligible for participation in the study if ANY one of the following criteria applies:

- The flock is in a poor state of nutrition or general health as determined by the Investigator.
- Members of the flock exhibit pre-study complicating disease conditions that may interfere with or prevent the evaluations and analyses in this study.
- Any other means of local population control (round-ups, egg addling, egg oiling) were used at the site within 3 months prior to the study or are scheduled for use during the study period.
- The flock is in an area where human traffic around the bait stations causes concern of human contact or interference with the test bait.
- The flock is at a site with an unreliable water source or with extreme variations in water level.
- The flock is a migratory flock of Canada geese.

Baiting Strategy

Field personnel will begin to develop a baiting strategy to ensure that all geese have access to bait beginning approximately 14 days before the treatment period begins. The test bait will be administered orally via free-choice feeding. Untreated bait will be offered in bait stations (black rubber feed pans) at each site at dawn and will be removed from each site at dusk. During the first 7 days of acclimation, untreated bait or whole corn may be scattered around the bait station to entice Canada geese to approach the feed pans and consume bait. In the event that the geese are too neophobic to eat bait from feed pans (i.e., no untreated bait consumed over three consecutive days), a shallow hole in the ground will be made to place the feed pan such that the top of the pan is approximately level with the ground.

Bait stations will be established in a pattern that allows the entire site to be visited in a uniform, systematic manner allowing goose counts over the entire site to minimize risk of duplicate observations. It is anticipated that multiple bait stations (1 to 20) will be required at each study site to account for territory/bait defending behavior exhibited by dominant geese in the resident flock. Modifications to the baiting strategy, such as the location and number of bait stations, may be made during the pre-baiting period to assure as many geese as possible from the flock consume the untreated bait used for acclimation. The final baiting strategy developed at each site will be described in detail on the Final Baiting Strategy Form and will be reported in the final study report, as will any changes in the baiting strategy that are required during treatment. Bait pan locations will be recorded with hand-held GPS.

The study schedule at each site will be initiated such that acclimation with untreated bait will end and application of test bait will commence approximately 14 days prior to when the first egg is expected to be laid (based on observed pairing and mating behaviors). The exact time for changing to test bait will be determined by the field personnel through behavioral observations of changes in pair bonding and mating behavior and by review of records of nesting in previous years (not available for all sites). Test bait will be provided in number- and color-coded bags to maintain treatment blinding. Treated (2500 ppm nicarbazin) and control baits (0 ppm nicarbazin) will not be visibly distinguishable from one another. Treated bait will be provided at each site for approximately 42 days.

<u>Determination of Bait Consumption</u>
Treated test bait consumption will be measured to assess drug intake. Once an initial baiting strategy is determined, acclimation with untreated bait will include daily weighing of uneaten bait from each bait station beginning 7 days prior to treatment. Feed pans will be used as bait stations to prevent spillage of bait and to allow easy collection of uneaten bait for re-weighing. Bait that has been dropped outside the pan will be collected daily for inclusion in the weighing procedure to determine the amount of bait eaten. Bait consumption will be measured by pre-weighing the bait provided at each station and gathering the remaining bait for weigh-back after the geese have been fed bait from dawn to dusk. Electronic top-loading balances (i.e., Ohaus © Portable Scout II Series S-6000) will be provided to each study site. Weighing procedures are outlined in SOP IE 002.00. Bait application records will be kept on the Daily Bait Accountability Record form.

Initial bait amounts offered will be based on the number of Canada geese on the site, offering 50g of bait per goose on the site during Acclimation Period Phase I. Amounts of bait offered following Acclimation Period Phase I will be calculated based on the amount of uneaten bait retrieved from the previous feeding during subsequent study periods. After retrieval of bait remaining from the previous feeding, bait will be weighed to determine the amount of bait uneaten at each bait station. Bait amounts for the subsequent feeding will be determined for the following day based on the amount of bait remaining from the previous feeding. At each bait station, the amount of bait to be offered will be calculated to provide approximately 750 grams of bait added to the amount of bait consumed the previous day during Acclimation Period Phase II. If there is routinely 750 grams or more bait retrieved from any bait station, the amount of additional bait offered may be reduced to adding an additional approximately 500 grams of bait to the amount eaten the previous day.

Each study site will also have a sentinel bait station at which metal mesh screening will be used to block access to the bait. This sentinel bait station will have bait (100 g) applied and removed on the same schedule as the other bait stations at the site. Weigh back of sentinel bait will be used to address variation in bait weight attributable to moisture accumulation or moisture loss, soiling of the bait, etc. Final calculations of amounts of bait consumed will include necessary mathematical corrections as a percentage determined by weight change in bait retrieved from the sentinel bait station.

Determination of Flock Size

The approximate size of the resident flock will be determined at each study site during the study. Once untreated bait has been applied at all of the bait stations, field personnel will follow the same pattern of travel used to apply bait for a second time to observe the area of the bait station [for at least 10 minutes] and record the number of geese visiting the station and the area of the station. If visibility of the areas surrounding more than one bait station overlaps such that all geese in the area of each bait station are visible from one bait station, only one count will be made encompassing those bait stations and surrounding areas to avoid double-counting of individual geese. Flock counts will be recorded on the Daily Flock Count Record. After the counts are made, the birds will be further observed for any evidence of abnormal health (anorexic, unthrifty, injured birds, etc.), or adverse or potentially confounding events (animals other than geese consuming the bait; predators, loose dogs, dead animals in vicinity; adverse environmental conditions, flooding; food supply changes, etc.). Behavior and health observations will be recorded on the Daily Flock Behavior and General Health Observation Record. Adverse events will be recorded on the Adverse Event Report.

Pairing/Mating Behavioral Observations

Observations of pairing behavior in the flock will be made upon approach and while at the flock site. Indications that geese are beginning to form pairs include subtle behaviors such as males defending females within a large flock. Typically, a pair of geese will separate itself from the rest of the flock and will begin to defend a territory, which will often include the nest site, a water source, and a food source. The location and number of baiting stations may be changed to accommodate the defense of territories of breeding pairs of geese if necessary at any time during the study. Observations of pairing behavior will be recorded on Daily Behavior and General Health Observation Record.

Mating behavior is typically a stereotyped sequence of events in Canada geese. Prior to mating, both the male and female will take mouthfuls of water and throw them over their backs without the wing movements that normally accompany bathing. Mating takes place on the water with the female in the normal floating position with her neck outstretched near the surface, and the female often becomes fully submerged for the few seconds of copulation. Following mating, the pair stretch their necks upward, raise their bills high and may rotate to face one another. Observations of mating behavior will also be recorded on Daily Behavior and General Health Observation Record.

Collection of Reproduction Activity Data

The proposed indication for the product is "reduction in hatching of eggs laid by local Canada goose flocks." Flock counts (adults and yearlings) and bait consumption measurements will be conducted to allow determination of the average bait consumption per goose at each study site to allow calculation of an average dose of nicarbazin per goose per day. Daily egg counts of the total number of eggs per clutch and the number of eggs that hatch per clutch, will yield hatchability data required to evaluate the label claim.

Determination of the locations of nests at each study site will begin at Day 0 of the study. Nests will be located by field personnel by performing a systematic sweep around bodies of water that cover the area from the shoreline to 50 feet from shore. Nests will be marked using a two-colored system (see following paragraph), and monitored nests will labeled with a code indicating site and number of the nest. Nests will be numbered numerically in the chronological order in which they are found. Nest locations and codes will be recorded on the Nest Location Record and locations will be taken using hand-held GPS.

Nicarbazin reduction in egg hatchability correlates with egg dinitrocarbanilide (DNC) levels. Previous studies with Canada geese have shown that peak plasma DNC levels are not reached until the fourth consecutive day of dosing. Studies in chickens have shown that the main reservoir of DNC in the egg is the egg yolk. Deposition of lipids and cholesterol into the egg yolk occurs primarily in the rapid growth phase occurring within the ovarian follicle 6-11 days prior to ovulation, which is also likely to be when the majority of DNC would be incorporated into the yolk. Treatment of chickens with nicarbazin has shown that treatment for 6 days is required before consistent levels of DNC in the egg are obtained (Furusawa, 2001) and that treatment for 8 to 10 days is required to reach maximum DNC levels in the egg (Jones et al., 1990). Effects on eggs laid by nesting Canada geese would not be seen until at least day 10 of dosing when the 4 day lag in achieving high plasma DNC levels is combined with a minimum 6 days prior to ovulation rapid growth period. Including nests with eggs laid prior to day 10 of treatment may skew hatchability data due to this effect. Therefore, nests in which eggs are laid prior to day 10 of treatment and nests in which egg-laying is not completed by Day 52 of the study will not be monitored for number of eggs or hatchability data. Nests to be included in hatchability monitoring for the study will be marked with fluorescent green flag stakes or flagging tape. Nests that are not to be monitored as determined by the above nest exclusion criteria will be marked with fluorescent orange flag stakes or flagging tape. Marking or flagging of nests will be placed at a distance away from the nest to avoid attracting predators.

Once nests are located, nests will be checked for eggs every other day until day 23 of incubation. At day 23 of incubation, nests will be checked for eggs daily. Egg counts will be performed in a systematic manner that follows a systematic path similar to that used for nest location and bait application rather than in chronological order. Eggs will be marked in multiple places on the egg shell in permanent marker with the code indicating site and nest number and with the date found.

Estimated hatching dates will be calculated as 28 days from the date the last egg in a clutch is laid. Egg counts will continue until 5 days beyond the latest estimated hatching day for the clutch. If the female abandons the nest after incubating for 20 or more days, any eggs that remained would be considered as not hatching. A nest will be considered abandoned if the eggs are not covered and the female is not observed in attendance of the nest for 2 consecutive egg counts. Any eggs that do not hatch or any eggs in nests that are abandoned may be collected for future analyses that would be amended to the study protocol. Egg counts and hatchability will be recorded on the Egg Counts and Hatchability Record. Monitoring of all nests will conclude on day 85 of the study.

Non-target Species Monitoring

Video cameras will be utilized at each study site to monitor and record potential visits of non-target species to the bait stations. Video monitoring will occur every third day at each study site when pre-bait or treated bait is present. Video taping will be continuous from the time the bait is placed in the morning until the bait is removed in the evening. This monitoring schedule will result in 252 observation hours per site, totaling 2,520 hours for the entire study (10 sites).

Upon viewing tapes, all visits by non-targets will be recorded. Observations will include species, time spent at bait station, time spent feeding on bait, and the time of day visitation occurred. These video observations will also be beneficial in determining goose foraging behavior and optimal baiting strategy.

Additionally, non-target reproductive activity in the area will be monitored. Weekly searches for nests of non-target birds will be made and locations of nests will be recorded. Nests of non-target birds will be monitored weekly to determine the status of eggs laid by non-target species (i.e. incubating, hatched, etc.). In the event that a non-target nest is abandoned or eggs remain unhatched beyond the normal incubation period, eggs from that nest may be collected and opened to determine fertility and may possibly be used for subsequent chemical analyses to determine whether nicarbazin residues are present.

Flock Health and Adverse Events

Because nicarbazin has been used for decades to control coccidiosis in the chicken broiler industry, the adverse effect of nicarbazin is best understood in chickens. In the southeastern U.S., where ambient air temperatures and relative humidity are high, there have been reports of heat stress in treated birds housed in factory scale production facilities. In preparation for this study, numerous studies (laboratory and field studies) have been conducted on many species (including geese, ducks and quail), and no evidence of heat stress or other adverse effect has ever been noted. Since this study will be conducted on wild goose populations in Oregon (significantly lower ambient temperatures and relative humidity than the southeastern U.S.), heat stress is not likely to occur and no other adverse effects are anticipated. However, in the event a sick or injured bird is discovered, the following methods will be in place to adequately document the event.

During flock counts and baiting, the Field Personnel and Investigator will observe the flock and note any adverse events (AE) including poor health, injury, etc. Additionally, Dr. Jack Mortensen will serve as a supervising veterinarian for this study and will make periodic inspections of the flocks as needed. In the rare event that a ill or injured bird is discovered, the bird will be trapped (hand or hand net) and the attending veterinarian, Dr. Jack Mortensen, will be consulted and the situation will be addressed under his direction. All information around that event will be recorded on the Adverse Event Report. As soon as possible after detecting a possible AE and, if applicable, determining a need for treatment, Field Personnel will report the AE to the Investigator and the Study Director as soon as possible, particularly in the event of 1) a serious event, 2) an unusual frequency of events, 3) illness or injury, or 4) death, even if the AE does not appear to be drug-related. The Investigator will document and describe the AE, categorize the magnitude, identify concomitant therapy and procedures, and evaluate the potential relationship of the AE to the drug article and therapies, as follows:

Magnitude of Adverse Effects (AE)

Score 1 = Mild	Score 2 = Moderate	Score 3 = Severe
• Bird alert, moves freely with few or no apparent physical or mental limitations • Signs intermittent or continuous. • Baseline social, feeding, and flight functions unhindered. • No evidence of affecting overall health. • Drug therapy and/or clinical procedure not necessary.	• Some physical discomfort or lethargy, bird shows pain-related or pain - avoidance behavioral changes. • Signs intermittent or continuous. • Baseline functions of mentation (mental activity) and/or physical mobility moderately decreased. • Possibly could affect overall health. • Drug therapy and/or clinical procedure may be necessary.	• Severe physical discomfort or decreased mental alertness. • Signs continuous. • Baseline functions severely hindered or prevented. • Long –term survival unlikely. • Drug therapy and/or clinical procedure imperative.

Relationship of Adverse Effects (AE) to Drug Article or Concomitant Therapy

Score 1 = Unknown	Score 2 = Unlikely	Score 3 = Possible	Score 4 = Probable
	Unlikely since AE is clearly pre-existing or caused by specific extraneous event, with no other causative factor evident.	Possible based on type, time course, and relationship of AE to dosing and external events. AE follows known response pattern for treatment, but AE could have been produced by animal's clinical state and/or other therapy.	Probable based on type, time course, and relationship of AE to dosing and external events. AE follows known response pattern for this treatment, with no other causal factors apparent. (Includes overdoses.)

Necropsy

Attempts will be made to recover any birds that are found dead during the course of normal study site monitoring. If deemed necessary to determine cause of morbidity or death, a routine postmortem examination will be conducted on any animal which dies spontaneously or is euthanized prior to study completion. Necropsy will include a complete gross examination for pathologic changes. Consideration will be given to wildlife policies existing at the site for decisions regarding recovery of any bird found dead during the course of the study. Carcasses will be disposed of in accordance with local regulations.

11. Experimental Design and Statistical Analyses:

Statistical analyses for this study were provided by and will be performed by a statistician contracted by [redacted] for this study.

Name: [redacted]
Company:
Address:

Tel/Fax/Email:

Experimental Design

The study is designed as a multi-site, blinded, field trial involving a single concentration of nicarbazin provided daily with randomization of flocks to two treatment groups (Treated and Control). The Investigator will have access to five separate Canada goose flocks (study sites) in each geographic area and will have adequate field personnel to obtain the required data at the five study sites. At each geographic area, two [of five] flocks will be designated as control flocks where geese will receive control bait. Three [of five] flocks will be designated to receive treated bait. Investigators and field personnel will be blinded as to the type of bait administered at each site. The study will be conducted simultaneously at the five locations in each geographic area.

Blocking Factors

The flocks will be ranked according to total flock size, as determined by the acclimation period flock counts, to form two size-strata within each of the two distinct geographic regions: (1) the smallest two or three flocks; and (2) the remaining three or two flocks. The number of flocks in these two size-strata (i.e., 2 and 3 or 3 and 2, respectively) will be based on maximizing the homogeneity of the flock sizes within the two size-strata.

Randomization Procedures

The two treatments will be randomized to the eligible flocks within the two flock-size strata with the restriction that one and only one flock within both the small and large flock-size strata receives the control bait. For example, if the small flock-size stratum contains two flocks and the large flock-size stratum contains three flocks, the control bait will be randomly assigned (via computer program) to one of the two flocks in the small flock-size stratum and to one of the three flocks in the large flock-size stratum; as a result, the remaining flock in the small flock-size stratum and the two remaining flocks in the large flock-size stratum will thus receive the treated bait.

Blinding of Product Identity

Extent of Blinding

All field personnel at the study sites will be completely blinded to treatment group designations throughout the study. Sponsor Representatives, the Study Director, and Quality Assurance officer will be aware of treatments during the study.

Blinding Method

Blinding will be accomplished by providing nicarbazin-treated and untreated test bait indistinguishable from each other to the study sites in number and color-coded packaging.

Access to Treatment Assignments

The Study Director and Sponsor Representatives will not be blinded to treatment group designation and will hold the blinding designations to be disclosed to study site personnel in the event of a medical emergency. The Investigator may be unmasked to treatment groups if a human or animal medical emergency requires disclosure of the treatment regimen. If unblinding becomes necessary, the Study Director or Sponsor Representatives will be contacted to disclose the treatment of the flock in question.

Experimental Unit

An eligible flock of free-ranging Canada goose, containing at least 10 breeding pairs, will be the experimental unit for the study while a clutch of eggs laid by a resident goose within that flock will be the experimental sub-unit for the study.

Number of Replicates per Treatment

A total of five flocks in each of two geographically different areas (total of 10 flocks) will be enrolled in the study. At each geographical area, three flocks will receive test bait and two will receive control bait. Within each flock, a minimum of 10 clutches laid by breeding pairs is expected, thereby resulting in a minimum expected 40 replicates of the control bait and a minimum of 60 replicates of the test bait.

Calculation of Derived Date

An egg hatching index will be determined for each individual clutch at a site as the ratio of the number of eggs hatching and the number of eggs incubated to the estimated hatching date. It is realized that large fluctuations in numbers of geese at a site could occur due to immigration and emigration of adults and non-breeders from adjacent non-treated areas. Use of the median number of observed adults should account for this fluctuation in goose numbers. An assumption behind the measure is that the proportion of reproductively immature or naturally non-breeding adults is the same among sites. In addition, it is assumed that predation is equal among sites.

Statistical Methodology

The egg hatching index (described in section 9.1.2.2) will constitute the primary efficacy parameter. The null hypothesis is that there will be no difference in the percentage of eggs hatched per clutch between treated and untreated sites. Data on the egg hatching index – or an appropriate transformation of the egg hatching index (e.g., logit or arcsine-square root) – will be statistically evaluated via mixed-model analysis of variance (ANOVA) with treatment (test or control), geographic region, and flock-size (small or large) as fixed effects and flocks within geographic regions as a random effect, including all interactions of the three fixed effects; the residual site variation (2 degrees of freedom) will be pooled with the inter-clutch variation in the ANOVA model for estimation of "random error". In order to obtain the least-squares estimate of treatment effect at each of the two geographic areas, area (i.e., geographic area) will be included in the ANOVA model as a fixed effect. Further, interaction terms – particularly those involving flock-size – may be omitted from the final ANOVA model if found to be statistically insignificant ($p>0.25$). In the event that an interaction involving "Treatment" (e.g., the interaction between treatment and area) is found to be statistically significant ($p\leq0.05$), the two treatment means within each level of the secondary fixed effect will be compared statistically via application of Fisher's least-significant-difference procedure. Data on test bait consumption (described in protocol section 9.2.1.4) will be statistically evaluated via the same ANOVA procedure to assess appropriate drug consumption. Additional statistical analyses may be conducted if deemed warranted; for example, the ANOVA of data on the egg hatching index might be repeated 'weighted' for the number of eggs per clutch and/or including covariate(s), such as the site area, amount of bait consumed, and number of clutches per site.

Data on adverse events, including flock health observations and non-target visitation to bait pans, will be summarized by treatment, as well as by study site and geographic location, to facilitate evaluation. All statistical analyses will be conducted using commercially available software, such as SAS®, SPSS, and Minitab. All statistically analyzed data will be provided to the EPA in ASCII, Excel, or SAS format(s) along with all of the other SAS files used for analyzing the data.

<u>Statistical Results</u>
The final determination of effectiveness is the reduction in the percentage of eggs hatching per nest at treated flocks versus the control flocks. Specifically, a reduction of 50% in hatchability as compared to control sites is efficacious.

12. Environmental Conditions:
Canada geese will be studied in their natural environment and will be subject to local environmental conditions. Temperature and relative humidity will be recorded at each site using Hobo Data Loggers. Natural disasters or atypical weather conditions (late season snowstorms, hailstorms, excessive rain, floods, etc.) will be documented in the study records and impact on the study will be considered. A description of each study site will be generated for the study files and will include feeding areas, watering areas, bait station areas, percentage cover, and a map including locations of bait stations, water, nests, etc.

13. List of Standard Operating Procedures (SOPs):
AD 001.01 Standard Operating Procedures
AD 004.01 Archiving Studies
AD 005.01 Archives
AD 007.01 Final Reports
AD 008.01 Personnel Qualification Records
AD 009.01 Institutional Animal Care and Use Committee
AD 011.02 Data Recording and Correction
AD 012.01 Test, Control, and Reference Substance Chain of Custody
AD 014.00 Adverse Incident Reporting to FIFRA 6(a)(2) A Guidance Document for Study Directors
HS 001.01 Chemical Spills, Exposures, and Emergencies
HS 004.00 Personal Protective Equipment
HS 007.00 Safe and Effective Handling of Contaminated Laboratory Items
HS 008.00 Hazard Communication
CH 002.00 Calculations, Significant Figures, and Rounding
CH/CO 001.01 Chemical Accountability and Tracking System
IE 002.00 Balances

IE 003.00 Class S Weights and QC Check Weights
IE 014.00 Analytical Instrumentation
IE 013.00 Security for Automated Data Collection Systems
LP 002.00 Sampling of Grain Baits and Concentrates for Chemical Analysis

14. List of Records to be Maintained:

Personnel List and Signature Form
Communication Record
Amendment to Study Protocol
Note to File Form
Protocol Deviation Form
Study Site Description Form
Flock Description Form
Flock Random Allocation Form
Flock/Study Site Removal Record
Daily Bait Accountability Record
Nest Location Record
Daily Egg Counts and Hatchability Record
Daily Flock Behavior and General Health Record
Daily Flock Count Record
Adverse Event Report
Temperature and Relative Humidity Records
Statistical Records
Necropsy Records (if needed)
Video Viewing Records

Please note that separate forms for each individual study size will be customized such that the study site is indicated in the header on each form. In the header, the person filling out the form will enter the appropriate information as to name, signature, date, and time.

15. Permits/Certifications:

Department of the Interior U.S. Fish and Wildlife Service Federal Fish and Wildlife Permit number MB019065-5 Amendment issued to Richard D. Curnow, Director of the NWRC, authorizes the scientific collection of up to 600 Canada geese in the state of Oregon.

State of Oregon Department of Fish and Wildlife Scientific Collection Permit will be issued to Kimberly Bynum to authorize conduct of this study with local resident Canada geese.

16. Endangered Species Act Compliance: Include the following statement:

Is there a possibility that the study, as proposed, will or may affect threatened or endangered species?

Yes:_____ No:_X____

17. National Environmental Policy Act Compliance:

Does the study, as proposed, have the potential for significant impact on the environment?

Yes:_X___ No: ______

Because this study has the potential to significantly impact the environment, an Environmental Assessment (EA) was conducted. The analysis in the EA led to a "Finding of No Significant Impact" (FONSI). The EA and FONSI will be released for public comment shortly. All NEPA documentation will be filed prior to onset of this study.

18. Employee Safety:

Employees will take precautions to avoid unnecessary exposure to nicarbazin, although the drug is not hazardous to humans. Non-Latex exam gloves will be provided to all field personnel for use during handling of bait being both offered and retrieved. Employees will also take necessary precautions to avoid exposure to potential pathogens in Canada goose feces by wearing gloves and following appropriate hand-washing procedures.

HS 004.00 Personal Protective Equipment

19. Schedule:

Proposed dates for the study:

Experimental Start:	February 2004
Experiment Termination:	July 2004
Study Completion:	December 2004

20. Staffing:

Positions	FTE FY2004
Research Manager	0.05
Program Assistant	0.05
Registration Manager	0.10
Registration Specialist	0.05
Project Leader	0.10
Reproductive Physiologist/Study Director	0.90
Biological Technician	0.05
Avian Physiologist	0.025
Wildlife Biologist (NWRC)	0.30
Wildlife Biologists	
Field Personnel (10-12 AD 120 day Appts. through WS OR)	1.00
Wildlife Biologists (USDA/APHIS/WS OR Personnel)	0.30

21. Principal Investigators, Cooperators and Consultants:

Investigator
Gary (Charlie) Weaver and Michael T. Slater
Wildlife Biologists
USDA APHIS WS, Operations, Oregon State
6135 NE 80th Avenue Suite A8
Portland, OR 97218

Co-Sponsor Representative [redacted]

22. Related protocols: QA-990, QA-999, QA-1035, QA-1085

23. Cost Estimate for Each Fiscal Year:

24. Staff qualifications:
The Study Director will ensure that personnel conducting procedures in this study are appropriately trained and qualified in those procedures, and that education, experience, and training are documented and maintained for all individuals participating in the study. All study participants will have documentation on file, which verifies their training and qualifications for the work they will perform in this study, including SOP training logs. All SOPs and study specific training logs will be completed and documented in study or personnel records prior to study participation in that aspect of the study.

25. Archiving:
All raw data, documentation, records, protocols, specimens, correspondence and other documents relating to interpretation and evaluation of data, and final reports generated as a result of this study will be retained in the archives of the National Wildlife Research Center at Fort Collins, Colorado.

26. Protocol Amendments:
Any changes in or deviations from this protocol will be documented on the Study Protocol Amendment Form, reviewed by appropriate personnel (e.g., IACUC, IBC, ACP, QA, etc.), and signed and dated by the Study Director, and Research Program Manager and Sponsor. Amendments will be distributed to all study participants as appropriate.

27. References:
Furusawa. 2001. Transference of Dietary Veterinary Drugs into Eggs. Veterinary Research Communications. 25:651-662

Jones, J.E., J. Solis, B.L. Hughes, D.J. Castaldo, and J.E. Toler. 1990. Reproduction Responses of Broiler-Breeders to Anticoccidial Agents. Poultry Science. 69: 27-36.

Palmer, R.S. (editor). 1976. Handbook of North American Birds Volume 2 Waterfowl (first part). New Haven and London, Yale University Press. Pp183-234.

Raveling, D. G. 1970. Dominance Relationships and Agonistic Behavior of Canada Geese in Winter. Behaviour. 37:292-318.

Van Wormer, J. 1968. World of the Canada Goose. Philadelphia: J.B. Lippincott Company.

28. Appendices:

Animal Use Appendix
Test, Control and Reference Materials/Device Use Appendix

Signature page:

________________________________ ______________
Study Director **Date**

Concur:

________________________________ ______________
Research Program Manager, NWRC **Date**

________________________________ ______________
Sponsor's Representative, [redacted] **Date**

Approved:

________________________________ ______________
Director, NWRC **Date**

Processing:
QAU Received: ________________ QAU Processed: ________________

IACUC -- see IACUC approval date in Animal Use Appendix
IBC -- see IBC approval date in Microbiological/Biohazardous Materials Use Appendix

Appendix I
Animal Use

Definition of animal use includes manipulating the behavior of wild animals in their natural habitat.

A. Animal description:

1) Species: Canada geese (*Branta canadensis*)
2) Strain and substrain (if applicable): Giant and Western
3) Number and Sex: approximately 200-600 adult geese (males and females; ratio determined by the local resident flock at each site)
4) Body weight range: approximately 3-6kg
5) Age: adult (approximately 2-10 years)

B. Rationale for involving animals, for appropriateness of species, and for numbers: Justify each.

1) Rationale for involving animals: This study will determine the effectiveness of nicarbazin in reducing the hatchability of eggs laid by local resident flocks in Oregon. Only live animals can consume bait, absorb nicarbazin drug from the bait, select nest sites, build nests, breed and lay eggs, incubate eggs, and brood offspring. No alternatives are available.
2) Rationale for appropriateness: Canada geese are the target species to which nicarbazin contraceptive bait will be applied once the product is registered.
3) Rationale for numbers: The numbers of Canada geese will vary dependent on the flock size and number of Canada geese consuming bait at each site. The number of study sites used is required to achieve statistically valid results. Canada geese will be offered bait in their natural environment and will have a choice as to whether or not to consume bait with nicarbazin.

C. Source:

Wild Canada geese will be offered nicarbazin bait for consumption and will be monitored in their natural environment in Oregon.

D. Method of identification of animals:

No attempt will be made to identify individual Canada geese.

E. Trapping/Collecting:

At this time, the Pacific Region United States Fish and Wildlife Service is considering the prevention of hatching of eggs laid by local resident Canada geese a "take" or removal of individuals from the population and has therefore required and subsequently issued a scientific collection permit. Oregon Department of Fish and Wildlife is concurring with the USFWS position and is likewise requiring a scientific collection permit. Other than the prevention of hatching of eggs laid by Canada geese at the treated study sites, Canada geese will not be trapped or collected for this study.

No geese (or other animals) will be trapped/collected or otherwise handled during the normal course of the study. While no illness or other adverse effects due to nicarbazin are expected, in the event injured or otherwise ill geese will be captured by hand or with the aid of a hand net. Captured birds will be taken to the attending veterinarian, Dr. Jack Mortensen, will be consulted and the situation will be addressed under his direction.

F. Transport:
N/A

G. Handling/restraint:
N/A

H. Quarantine:
N/A

I. Housing/maintenance:
Canada geese will be studied in their natural environment and will be subject to local environmental conditions. Temperature and relative humidity will be recorded at each site using Hobo Data Loggers. Natural disasters or atypical weather conditions (late season snowstorms, hailstorms, excessive rain, floods, etc.) will be documented in the study records and impact on the study will be considered. A description of each study site will be generated for the study files and will include feeding areas, watering areas, bait station areas, percentage cover, and a hand-drawn map including locations of bait stations, water, nests, etc.

J. Disposition of animals:
Canada geese will remain in the wild as part of their local resident Canada goose flocks at the study sites at the conclusion of this study.

K. Duplication of prior studies:
This is the first study of nicarbazin used to prevent the hatching of eggs laid by local resident Canada goose flocks intended as proof of effectiveness of nicarbazin for registration purposes. This is the largest field study proposed to date and does not duplicate previous field studies in the concentrations of nicarbazin used in bait or the final outcome measures used.

L. Pain or distress:
Both Dr. Kim Bynum and John Eisemann spoke with the NWRC Attending Veterinarian (1/7/004 and 1/30/04, respectively) about the potential for pain and suffering of study subjects under this study. Dr. Gathright determined that the methods outlined in the protocol and the nature of the compound being tested posed no risk of unreasonable pain or suffering.

Name of Attending Veterinarian: Dr. Gordon Gathright
Date of Consultation: 1/7/04 and 1/30/04

1. <u>Alternative procedures</u>:
During nest monitoring to determine the number of eggs laid (clutch size) and the number of eggs that hatch, some Canada geese may experience momentary distress due to the proximity of field personnel to the nest during incubation/brooding. Personnel will minimize the amount of time spent at each nest, which should minimize distress. Distress that any Canada geese

experience is not expected to interfere in any way with attentiveness to the nest, incubation, or reproductive success.

2. **Justification for withholding sedatives or analgesics:**
Sedative or analgesic administration would not be appropriate for the above distress as it will not be extensive enough to require any form of sedation. Additionally, sedation would be more likely to interfere with the normal behavior of the Canada geese involved in the study than would the distress that may be experienced.

3. **Consultation with Attending Veterinarian:**
Attending Veterinarian Consultation: Gordon Gathright Date: 01/07/2004

M. IACUC approval:
Date of IACUC Approval Letter: 02/02/04

Appendix II
Test, Control and Reference Material/Devices Formulation and Use

NOTE: Final control and treated bait formulation information will be amended to the study protocol prior to onset of the study.

A. Describe the test material:
As appropriate, provide the chemical, bait or device:

1) Name or code: [redacted]

2) Concentration and purity: 2500 ppm nicarbazin
Provided as [redacted]

3) Source: Name: [redacted]
Address:

4) Batch number: Study will include multiple batches as required.

B. Describe any control or reference materials/devices:
Pre-formulated bait provided by [redacted] as treated or control bait. The bait formulation will be detailed in the study records.

C. Carriers, mixtures and material preparation:
Bait formulation will be described in the study records.

D. Route of administration:
Study bait will be administered ad libitum as daily feed available to study animals for up to 42 days.

E. Dosage:

Nicarbazin concentrations may be as high as 2500ppm in bait offered. Dose of nicarbazin per animal will be determined by the amount of bait consumed by each individual animal. If target 25 grams per Canada goose is achieved, each goose will consume 62.5 mg nicarbazin, which is 15.625 mg/kg nicarbazin for the average 4 kg Canada goose.

F. Test, control, and reference substance (TCRS) accountability:
Bait will be tracked according to SOP AD012.02 Test, Control, and Reference Chain of Custody.

G. Material verification:
Study baits will be analyzed for DNC levels by [redacted] and Certificates of Analysis will be archived with the study. Analyses will include prior to shipment, during the study, and at the conclusion of the study.

TCRS Custodian Consultation: Jerome Hurley **Date:** 01/07/2004

APPENDIX C

Environmental Toxicity Study Summaries

Summaries provided by [redacted] based on the confidential dossier submitted in 1997 for Joint Expert Committee on Food Additives (JEFCA) evaluation of nicarbazin as a Veterinary Drug with a Long History of Use as part of the Codex Alimentarius process to establish an international accepted daily intake and maximum residue level for nicarbazin.

Study: The acute toxicity of 2-hydroxy-4,6-dimethylpyrimidine and 4,4'-dinitrocarbanalide for some aquatic organisms

Date: 6/27/1977

Summary:

The acute toxicity of 2-hydroxy-4,6-dimethylpyrimidine (HDP) and 4,4'-dinitrocarbanalide (DNC) was measured for unicellular algae (*Chorella pyrenoidosa*), water flea (*Daphnia magna*), guppy (*Poecilia reticulate*), and rainbow trout (*Onchorhyncus mykiss*; *Salmo gairdneri*). Measurements included observation of the test organisms as well as water pH and oxygenation. Water pH and oxygenation did not significantly differ between test and control. The acute toxicity of HDP was low, and no toxic effects were observed for DNC at its maximum solubility in water of 20 µg/l.

Methods:

***Chorella pyrenoidosa*:** Test compounds were dissolved in medium in which cells of Chlorella pyrenoidosa normally proliferate rapidly. HDP was tested at concentrations of 1,000-10,000 mg/l. DNC was tested at its maximum solubility (20 µg/l) by first dissolving the DNC in acetone and then preparing the test medium. Control cultures were prepared including acetone for tests with DNC. Medium (100 ml) was inoculated with 10^6 cells of Chlorella pyrenoidosa and then illuminated with 4000 lux intensity light at 20°C. The numbers of algal cells were determined using a Coulter Counter at days 2, 3, and 4 post-inoculation.

***Daphnia magna*:** Test compounds were dissolved in standard reference water, which is a suitable medium for culture of Daphnia magna. HDP was tested at concentrations of 1,000-10,000 mg/l. DNC was tested at its maximum solubility (20 µg/l) by first dissolving the DNC in acetone and then preparing the test medium. Control cultures were prepared including acetone for tests with DNC. Daphnids (n=25) cultured in the laboratory and known to be less than 24 hours old were cultured in 250 ml of medium at 20°C. Daphnids were not fed, and dead daphnids were counted and removed at 24 and 48 hours. Medium pH and oxygenation were measured at 0 and 48 hours.

***Poecilia reticulate*:** Test compounds were dissolved in hard A & A water containing 300 mg/l of sodium chloride, which is a medium suitable for culturing guppies. HDP was tested at 5,600-10,000 mg/l. DNC was tested at its maximum solubility (20 µg/l) by first dissolving the DNC in acetone and then preparing the test medium. Control cultures were prepared including acetone for tests with DNC. Laboratory-cultured guppies (n=10) of 3-4 weeks in age were cultured in 1:1 of medium at 24°C without aeration and without feeding. Medium was completely replaced each day. Dead guppies were removed and counted after 1, 2, 3, and 4 days. Medium pH and oxygenation were measured at the start, at each replacement of both fresh and used medium, and at the end of the test.

***Onchorhyncus mykiss* (*Salmo gairdneri*):** Test compounds were dissolved in soft A & A water, a medium suitable for trout. HDP was tested at concentrations of 3,200 mg/l and 5,600 mg/l. DNC was tested at its maximum solubility (20 μg/l) by first dissolving the DNC in acetone and then preparing the test medium. Control cultures were prepared including acetone for tests with DNC. Trout (n=10) were supplied by a hatchery and were cultured in 1:1 of medium at 15°C with aeration. Trout were not fed during the test. Dead trout were removed and counted after 1, 2, 3, and 4 days. Medium pH and oxygenation were measured at the start, at each replacement of both fresh and used medium, and at the end of the test.

Results:
HDP did not affect pH of the test medium except a slight effect at the highest concentrations. DNC did not affect pH of the test medium. Oxygenation of test medium did not fall to less than 85% saturation in any test. The tested concentrations of HDP and DNC tested did not affect growth of Chlorella pyrenoidosa as compared to control cultures. The LC_{50} value for DNC was not reached in any test. The LC_{50} of HDP was not reached in rainbow trout during the test. The LC_{50} of HDP in Daphnia magna was determined to be greater than 10,000 mg/l at 24 hours and 7,500 mg/l at 48 hours. The LC_{50} of HDP in guppies was determined to be greater than 10,000 mg/l until 96 hours, at which point the LC_{50} was 10,000 mg/l.

Study: Summary Report: A Greenhouse Study to Determine the Rate of Decline of Soil Incorporated Ionophore and ^{14}C Nicarbazin Singly and In Combination

Date: (unknown)

Summary:
Data for the ionophore tested is not shown.

This study was conducted to determine the rate of degradation of soil-incorporated 10 ppm ^{14}C nicarbazin. The levels of radioactivity in the ^{14}C nicarbazin-treated soils were followed to determine if there was any microbiologically-mediated terminal oxidation of the labeled compound or subsequent labeled degradation products. The study was conducted over a period of 1 year in a greenhouse under ambient temperature and photoperiod. Test compounds were mechanically blended into weighed portions of dry non-sterile soil which was then brought to a moisture content of approximately 75% of field capacity. Soil flats were enclosed in plastic bags to prevent rapid fluctuation in soil moisture levels. Initial and periodic samples of control and test soils were taken, air-dried, finely ground with mortar and pestle, and assayed for nicarbazin and ^{14}C radioactivity. Nicarbazin soil levels remained unchanged for a period of two weeks, after which degradation proceeded slowly. By 18 weeks, values stabilized at approximately 72% degradation and remained unchanged thereafter through the end of the 52 week study period. Over the study period, ^{14}C radioactivity values did not change, indicating that soil microorganisms did not metabolize a significant portion of the ^{14}C nicarbazin or other volatile products.

Study: Summary Report: A Study to Determine the Rate of Depletion of Ionophore and ^{14}C Nicarbazin in a Field Soil Plot

Date: (unknown)

Summary:
Data for the ionophore tested is not shown.

This study was conducted to determine the rate of degradation of ^{14}C nicarbazin incorporated into the soil of a field plot (Greenfield, Indiana) and exposed to natural ambient weathering for a period of 1 year. Test compound was incorporated into the top 3 inches of soil at a concentration of 2.47 kg/ha (1kg/A). Test and control plots were each confined to the soil within a 3 foot diameter section of galvanized metal culvert. Test plots were maintained free of weeds by cutting any weed seedlings at the soil surface. Soil from field plots was sampled periodically to a depth of 15 cm (6 inches) using a Hoffer soil coring tube. Each sample was a composite of four random cores of soil which were air-dried and assayed for nicarbazin and ^{14}C radioactivity. Radioactivity concentration in the test plot remained constant over the one year test period, indicating that (1) ^{14}C nicarbazin or labeled degradation products did not leach beyond the 15 cm sampling depth and (2) soil microorganisms did not metabolize significant quantities of ^{14}C nicarbazin to CO_2 or other volatile products. Nicarbazin degraded with a half-life of approximately 49 weeks as determined by linear regression analysis of the parent nicarbazin assay data.

Study: The Effects of Nicarbazin in Chicken Litter on Soil Nitrification

Date: 03/27/1985

Summary:
This study was conducted to determine the effects of litter from chickens fed nicarbazin on the soil organisms responsible for the nitrification steps of the nitrogen cycle when applied to the soil at the rate normally used in agricultural practice. Chickens were allocated to the following treatment groups: (1) normal diet days 0-56; (2) 125 ppm nicarbazin in normal diet days 0-35, then normal diet days 36-56; or (3) 125 ppm nicarbazin in normal diet days 0-50 and normal diet days 51-56. Litter mixtures from each group were collected at the end of the feeding period and mixtures were homogenized. Homogenized litter mixtures were then mixed with two soils, a clay loam and a sandy loam or known characteristics, at a rate of 0.64 g/kg, which corresponds to an application rate of 1.25 tons per hectare ploughed to a depth of 15 cm. At 0, 14, and 28 days, ammonium sulfate solutions were added to six replicates of each litter/soil mixture and then allowed to incubate for 3 days or 14 days prior to analysis of soil samples for content of ammonia, nitrite, and nitrate using an Orion ion meter and ion-specific electrodes. Comparison of litter/soil mixtures showed no significant differences between control and treated samples in levels of ammonia, nitrite, or nitrate, indicating that nicarbazin had no detectable effect on the soil microorganisms involved in the nitrification steps of the nitrogen cycle.

Methods:
Male and female Cobb broiler chicks (*Gallus gallus domesticus*) (n=25 males and 25 females) were obtained from a local supplier shortly after hatching. After arrival, chicks were assigned to treatment groups with seven males and seven females per group into the following treatments: (1) normal diet days 0-56; (2) 125 ppm nicarbazin in normal diet days 0-35, then normal diet days 36-56; or (3) 125 ppm nicarbazin in normal diet days 0-50 and normal diet days 51-56. Birds were housed by treatment in floor pens approximately 1.2 m by 1.5 m with concrete floors and galvanized steel sides located in a building which provided suitable environmental conditions (continuous lighting, average 31°C, average 70% humidity) for chicks. Wood shavings were provided as bedding such that over the course of the test, the final proportion of birds to litter

was 1.7 birds/kg litter. Feed and water were provided *ad libitum* at all times during the study.

Two soils, silty clay loam and sandy loam, were obtained for testing. Microbiological examination of each soil was done by extracting 10 g samples with 100 ml sterile distilled water in a Colworth Stomacher, preparation of serial 10-fold dilutions in sterile water, and plating of 100 µl aliquots onto Sabourand Dextrose Agar, Czapek-Dox Agar, and Tryptone Soy Agar. Plates were incubated at 25°C for 2 days and colonies were counted and recorded photographically.

Mixtures of soil and litter were to be prepared such that the amount of chicken litter added to the soil corresponded to a normal agricultural application of 12.5 tons per hectare of land ploughed to a depth of 15 cm, approximately 6.4 g litter/kg soil. However, a calculation error resulted in an application rate of .64 g litter/kg soil in this study. Soil/litter mixes were prepared in 2 kg quantities to which distilled water was added to bring the soil moisture content to 60% capacity. Soil/litter mixes were transferred into 36 replicates of 20 g in 8oz. bottles and sealed with screw-cap lids. Filled bottles were incubated at 21-22°C and weighed daily to facilitate adjustment of moisture content due to moisture loss over time.

Six replicates from each soil type were selected for addition of ammonia at days 0, 14, and 28. Following mixing, bottles were returned to incubation. After 3 days and 14 days incubation, 3 replicates were withdrawn for analysis. Soil/litter mixes were analyzed for content of ammonia, nitrite, and nitrate.

Results:
Soils contained a wide variety of bacteria, actinomycetes, and fungi, with no single type predominating. Soil analysis revealed no significant adverse effects on ammonia, nitrite, and nitrate levels, with a slight stimulatory effect on the conversion of nitrite to nitrate in soils mixed with litter from chickens treated with nicarbazin.

Study: Effects on Gas Production (Methane + CO_2) During the Anaerobic Digestion of Litter Samples Collected from Chickens Fed Diets Containing Nicarbazin

Date: 03/15/1985

Summary:
This study was conducted to assess of the effects of chicken litter samples from chickens fed nicarbazin on the microorganisms involved in anaerobic digestion by quantifying the amount of gas (methane + CO_2) produced in the process. Litter samples were collected from chickens fed a diet without nicarbazin and from chickens fed a diet with nicarbazin for 35 days or 50 days. The method used was a modification of the method of the Standing Committee of Analysts titled "Amenability of sewage sludge to anaerobic digestion" (Department of the Environment, UK, 1977). Litter collected from chickens fed a diet containing nicarbazin had a negligible effect on gas production during anaerobic digestion. Litter collected from chickens fed a diet containing nicarbazin for 50 days resulted in a 9-15% difference in gas volume produced during anaerobic digestion, but this difference was not statistically significant. Litter from chickens fed diets containing nicarbazin was found to be amenable to anaerobic digestion.

Methods:
Reference raw sludge was obtained from a sewage treatment plant and stored at 0-4°C. Seed sludge was

obtained from a laboratory anaerobic "breeder" digester that was fed with reference raw sludge. Samples of chickens litters and sludges were dried to a constant weight in an oven at 105°C. Dried samples were ashed at 700°C for 30 minutes. Appropriate volumes of reference raw sludge were added to duplicate digester bottles which were placed in the digestion apparatus water bath and allowed to equilibrate to a temperature of 35°C, at which time digesting seed sludge was added to each bottle. Litter samples were thawed and mixed, and aliquots were added to each test bottle. If needed, distilled water was used to adjust all bottles to the same volume and then bottles were stoppered and mixed by inversion. Bottles and gas collection tubes were connected with flexible tubing. Gas collection tubes with water were adjusted to the "0" mark with suction, then clips were closed and time was noted. Bottles were gently mixed twice daily during the incubation period to mix contents and release trapped gas bubbles. Reading of gas production were taken twice daily for 5 days. If a gas collection tube was nearly full, the reading was noted and gas was vented away allowing the water level to return to the "0" mark. At the conclusion of the test, heights of gas columns were converted to volumes and mean cumulative gas production were plotted against time. Mean cumulative gas production were expressed as percentages of the (1) reference raw sludge, and (2) the reference raw sludge with chicken litter from chickens fed diets that did not contain nicarbazin, during the period when gas production in the reference raw sludge was constant.

Results:
Neither treatment group of litter from chickens fed nicarbazin showed a statistically significant difference from either the reference raw sludge or the reference raw sludge with litter from chickens fed diets not containing nicarbazin. Litter collected from chickens fed a diet containing nicarbazin had a negligible effect on gas production during anaerobic digestion. Litter collected from chickens fed a diet containing nicarbazin for 50 days resulted in a 9-15% difference in gas volume produced during anaerobic digestion, but this difference was not statistically significant. Litter from chickens fed diets containing nicarbazin was found to be amenable to anaerobic digestion. Neither treatment group of litter from chickens fed nicarbazin showed a statistically significant difference from either the reference raw sludge or the reference raw sludge with litter from chickens fed diets not containing nicarbazin.

Study: Determination of the Toxicity of Nicrazin* and Supacox (Pancoxin Plus) to Eight Higher-Plant Species by Soil Application (*Note that Nicrazin is Nicarbazin)

Date: 07/1982

Summary:
Data for Supacox are not included here.

The effect of the food additive nicarbazin on the shoot growth of the following plant species was determined: oats (*Avena sativa*), corn (*Zea mays*), tomato (*Lycopersicon esculentum*), lettuce (*Lactuca sativa*), bean (*Phaseolus vulgaris*), turnip (*Brassica rapa*), pea (*Pisum sativum*), and sunflower (*Helianthus annus*). Concentrations of nicarbazin added to test soils were 0, 1, 10, 100, and 1,000 mg/kg. The concentration of additive in soil that reduces shoot growth by 50% (EC_{50}) was calculated. Nicarbazin was found to have no detectable effect on the growth of higher-plant species included in the test, with the exception of oats. In oats a non-linear response was observed where shoot growth was not significantly different except in the 10 mg/kg treatment group, which obviated the calculation of the EC_{50} value.

Methods:

Seeds of each plant species were purchased and batches of seeds were placed in Petri dishes containing moistened filter paper for germination in darkness at 20°C. Nicarbazin was initially mixed in a coffee mill with quartz sand to provide the dilution series to be tested. Each dilution was then thoroughly mixed with compost in the proportion of 10 g test mixture to 990 g of soil to provide the target concentrations of nicarbazin to be tested. Pre-germinated seeds (n=6 each) were placed at an approximate depth of 1.5 cm in each 7 cm plant pot containing the appropriate soil mixture in four replicates for each test concentration. Blocks of samples were randomized after planting and maintained in a plant growth room under a 16 hour photoperiod at 20°C for 14 days. Soil moisture content was adjusted to approximately 80% of the soil moisture holding capacity.

Results:

Daily records of any observable phytotoxic effects were recorded and fresh weight of plant shoots was recorded after 14 days incubation. The concentration of nicarbazin that could be expected to result in a 50% reduction in plant shoot growth (EC_{50}) was calculated graphically. No phytotoxic effects were recorded after seedling emergence. Data revealed that nicarbazin resulted in no significant effect in plant shoot weight between treated and control soils, except in the case of oats where a non-linear effect was noted (See Table 1).

Fresh Weight of Shoots (g)					
	Nicarbazin Concentration in Soil				
Treatment Replicate	1 mg/kg	10 mg/kg	100 mg/kg	1000 mg/kg	Control Soil
1	1.943	1.043	1.294	1.720	1.648
2	1.800	0.333	1.442	2.030	1.748
3	1.500	0.468	1.615	1.516	1.911
4	1.583	0.447	1.462	0.394	1.472
Mean	1.707	0.573	1.453	1.415	1.695
Standard Deviation	0.202	0.319	0.131	0.713	0.184

Additional Environmental Toxicity Study Summary

Provided by [redacted] based on confidential study reports not included in the JEFCA dossier.

Study: Nicarbazin Technical Acute Toxicity (LC_{50}) to the Earthworm

Date: Unknown

Summary: The purpose of this study was to determine the acute toxicity of nicarbazin to the earthworm in an artificial soil under laboratory conditions. Soil was comprised of industrial quartz sand, kaolin clay, and sphagnum peat. Calcium carbonate was added to give the soil a pH of approximately 5.7 and soil moisture content was 35% of the dry weight. Worms (n=240) were randomly allocated to treatment groups with four replicates of ten worms per treatment group. Treatment groups included 0, 95, 171, 309, 556, and 1,000 ppm nicarbazin in soil. Tests were conducted in 1L glass containers with 736 g wet weight of soil. Worms were weighed at the start of treatment and at the end of the 14-day observation period. No mortalities occurred and body weight changes were similar across all treatment groups. The LC_{50} of nicarbazin was determined to be >1,000 ppm, which was also considered to be the no observable effects level (NOEL).

Study: DNC (4,4'-dinitrocarbanilide) Acute Toxicity (LC_{50}) to the Earthworm

Date: Unknown

Summary: The purpose of this study was to determine the acute toxicity of DNC to the earthworm in an artificial soil under laboratory conditions. Soil was comprised of industrial quartz sand, kaolin clay, and sphagnum peat. Calcium carbonate was added to give the soil a pH of approximately 5.7 and soil moisture content was 35% of the dry weight. Worms (n=240) were randomly allocated to treatment groups with four replicates of ten worms per treatment group. Treatment groups included 0, 95, 171, 309, 556, and 1,000 ppm DNC in soil. Tests were conducted in 1L glass containers with 736 g wet weight of soil. Worms were weighed at the start of treatment and at the end of the 14-day observation period. No mortalities occurred and body weight changes were similar across all treatment groups. The LC_{50} of DNC was determined to be >1,000 ppm, which was also considered to be the no observable effects level (NOEL).

Study: HDP (2-Hydroxy-4,6-Dimethylpyrimidine) Acute Toxicity (LC_{50}) to the Earthworm

Date: Unknown

Summary: The purpose of this study was to determine the acute toxicity of HDP to the earthworm in an artificial soil under laboratory conditions. Soil was comprised of industrial quartz sand, kaolin clay, and sphagnum peat. Calcium carbonate was added to give the soil a pH of approximately 5.7 and soil moisture content was 35% of the dry weight. Worms (n=240) were randomly allocated to treatment groups with four replicates of ten worms per treatment group. Treatment groups included 0, 95, 171, 309, 556, and 1,000 ppm HDP in soil. Tests were conducted in 1L glass containers with 736 g wet weight of soil. Worms were weighed at the start of treatment and at the end of the 14-day observation period. No mortalities occurred and body weight changes were similar across all treatment groups. The LC_{50} of HDP was determined to be >1,000 ppm, which was also considered to be the no observable effects level (NOEL).

APPENDIX D

WHO and Other Published Summaries

Wells, Robert. Residues of Some Veterinary Drugs in Animals and Foods: Nicarbazin. Food and Nutrition Paper. Volume 41, Number 11: pp83-88. 1999.

Roberts, G. and the Joint FAO/WHO Expert Committee on Food Additives (JECFA). Toxicological Evaluation of Certain Veterinary Drug Residues in Food. WHO Food Additives Series: 41: pp115-122. 1998.